

Draft Comparative Effectiveness Review

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**Comparative Effectiveness of Case Management for
Adults with Medical Illness and Complex Care Needs**

Prepared for:

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting Comparative Effectiveness Reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see <http://effectivehealthcare.ahrq.gov/reference/purpose.cfm>

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design and/or methodological approaches do not necessarily represent the views of individual technical and content experts.

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Comparative Effectiveness of Case Management for Adults with Medical Illness and Complex Care Needs

Structured Abstract

Objectives: In this evidence review we evaluated case management (CM) as an intervention strategy for chronic illness management. We summarized the existing evidence related to the effectiveness of CM in improving patient-centered outcomes, quality of care, and resource utilization in adults with chronic medical illness and complex care needs. We also assessed the effectiveness of CM according to patient and intervention characteristics.

Data Sources: Articles were identified from searches of the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials, EBM Reviews, CINAHL (EBSCO), and Ovid MEDLINE®.

Review Methods: We used specifically developed inclusion and exclusion criteria to determine study eligibility and selected randomized controlled trials (RCTs) and cohort studies relevant to the use of CM in coordinating care for individuals with complex care needs. Of the 4,789 citations identified at the title and abstract level, we screened and reviewed 823 full-length articles. A total of 99 articles (based on 76 studies) were included. Eligible studies were quality rated and data were extracted, entered into tables, and summarized. Due to the heterogeneity of outcomes, meta-analyses were not conducted. Systematic reviews were retrieved for reference, but data from pooled results of published reviews were not included in our analysis.

Results: Overall, the interventions tested in the studies were associated with only small changes in patient-centered outcomes, quality of care, and resource utilization. Many of the published trials of CM examined programs that targeted specific patient conditions, and the effects of CM tend to be confined to isolated types of outcomes. While CM can improve some types of healthcare utilization, there are minimal effects on overall costs of care. Characteristics of successful interventions include intense CM with greater contact time, longer duration, face-to-face visits, and integration with patients' usual care providers, although studies of CM use a diversity of approaches in their programs.

Conclusions: Recognizing the heterogeneity of study populations, interventions, and outcomes, we sought to elucidate the conditions under which CM was effective. We found that CM had limited impact on patient-centered outcomes, quality of care, and resource utilization among patients with chronic medical illness.

Contents

Executive Summary	ES-1
Introduction.....	1
Background.....	1
Distinguishing Case Management from Other Interventions	2
Variability of Case Management Implementation	4
Scope and Key Questions	4
Methods.....	6
Topic Development and Refinement	6
Search Strategy	6
Study Selection	7
PICOTS Framework	7
Populations of Interest	7
Interventions	7
Comparators	8
Outcomes of Interest	8
Timing	8
Settings.....	9
Types of Studies.....	9
Analytic Framework	9
Data Extraction and Data Management	9
Quality Assessment.....	10
Data Synthesis.....	10
Grading the Body of Evidence for Each Key Question.....	11
Peer Review and Public Commentary	11
Results	12
Search Results.....	12
Overall Effectiveness of Case Management	15
Key Question 1a. In adults with chronic medical illness and complex care needs, is case management effective in improving <i>patient-centered outcomes</i> ?	16
Key Question 1b. In adults with chronic medical illness and complex care needs, is case management effective in improving <i>quality of care</i> ?	17
Key Question 1c. In adults with chronic medical illness and complex care needs, is case management effective in improving <i>resource utilization</i> ?	18
Key Question 2. Does the effectiveness of case management differ according to <i>patient characteristics</i> ?	18
Key Question 3. Does the effectiveness of case management differ according to <i>intervention characteristics</i> ?	19
Effectiveness of Case Management in Defined Patient Populations.....	20
Case Management for Older Adults with Multiple Chronic Diseases.....	20
Case Management for the Frail Elderly	30
Case Management for Patients with Dementia	35
Case Management for Congestive Heart Failure	48
Case Management for Patients with Diabetes Mellitus	57
Case Management for Patients with Cancer	67

Case Management for Patients with Serious Chronic Infections.....	74
Case Management for Other Clinical Conditions	81
Summary and Discussion	85
Limitations of this Review.....	85
Conclusions.....	87
Future Research	92
References	94
Abbreviations	103

Tables

Table A. Summary evidence table: Comparative effectiveness of case management for adults with medical illness and complex care needs	ES-10
Table 1. Features of case management programs	3
Table 2. Characteristics of case management interventions for older adults with multiple chronic diseases	23
Table 3. Characteristics and outcomes of studies of case management for older adults with multiple chronic diseases	28
Table 4. Characteristics of case management interventions for the frail elderly.....	32
Table 5. Characteristics and outcomes of studies of case management for the frail elderly	33
Table 6. Characteristics of case management interventions for patients with dementia	38
Table 7. Characteristics and outcomes of studies of case management for patients with dementia.....	45
Table 8. Characteristics of case management interventions for patients with congestive heart failure	49
Table 9. Characteristics and outcomes of studies of case management for patients with congestive heart failure	54
Table 10. Characteristics of case management interventions for patients with diabetes.....	59
Table 11. Characteristics and outcomes of studies of case management for patients with diabetes	65
Table 12. Intermediate health outcomes among trials of case management for diabetes.....	66
Table 13. Characteristics of case management interventions for patients with cancer	69
Table 14. Characteristics and outcomes of studies of case management for patients with cancer	72
Table 15. Characteristics of case management interventions for patients with HIV/AIDS or TB77	
Table 16. Characteristics and outcomes of studies of case management for patients with HIV/AIDS or TB.....	80
Table 17. Summary evidence table: Comparative effectiveness of case management for adults with medical illness and complex care needs	88

Figures

Figure A	ES-3
Figure 1. Adapted chronic care model.....	2
Figure 2. Analytic framework.....	9
Figure 3. Study flow diagram	13

Appendixes

Appendix A. Definitions of Case Management

Appendix B. Exact Search Strings

Appendix C. Inclusion and Exclusion Criteria

Appendix D. Defining Complex Care Needs

Appendix E. Quality Assessment Methods

Appendix F. Excluded Studies

Appendix G. Quality Assessment of Trials and Observational Studies

Appendix H. Evidence Tables: Case Management for Older Adults with Multiple Chronic Diseases

Appendix I. Evidence Tables: Case Management for the Frail Elderly

Appendix J. Evidence Tables: Case Management for Dementia

Appendix K. Evidence Tables: Case Management for Congestive Heart Failure

Appendix L. Evidence Tables: Case Management for Diabetes Mellitus

Appendix M. Evidence Tables: Case Management for Cancer

Appendix N. Evidence Tables: Case Management for Serious Chronic Infections

Appendix O. Evidence Tables: Case Management for Other Clinical Conditions

Appendix P. Strength of Evidence

Executive Summary

Background

Chronic diseases are the leading cause of illness, disability, and death in the United States.¹ Providing medical care for chronic illness is often complex, as patients require multiple resources, treatments, and providers. One strategy for improving the coordination and efficiency of care for chronic conditions is to develop programs that improve care coordination and implement care plans.²⁻⁴ Case management (CM) is one such supplemental service, in which a person, usually a nurse or social worker, takes responsibility for coordinating and implementing a patient's care plan, either alone or in conjunction with a team of health professionals.

CM tends to be more intensive in time and resources than other chronic illness management interventions, and it is important to evaluate its specific value. The coordinating functions performed by a case manager include helping patients navigate health care systems, connecting them with community resources, orchestrating multiple facets of health care delivery, and assisting with administrative and logistical tasks. These coordinating functions are distinct from clinical functions, including disease-oriented assessment and monitoring, medication adjustment, health education, and self-care instructions. Such clinical functions are often the defining aspects of other chronic illness management interventions. In the context of chronic illness care, they are central to the role of a case manager as well, but a case manager also performs coordinating functions.

CM is often utilized when such coordination and integration is inherently burdensome or challenging and difficult for patients to accomplish on their own. CM usually involves high-intensity engagement with such patients, and case managers often adopt a supervisory role in comprehensively attending to patients' complex needs.⁵ Conceptually, a case manager can be seen as an agent of the patient, taking a "whole-person" (rather than solely clinical or disease-focused) approach to care, and serving as a bridge between the patient, the practice team, the health system, and community resources.

The evolution of CM models in health care, and their expanding use in chronic illness management, has led to the term "case management" being used to describe a wide variety of interventions. As a result, there is no consensus about the core components of CM. Moreover, the term "case management" is often used interchangeably with other forms of chronic illness management interventions – such as "disease management" and "self-management support."

Individual CM programs usually are customized for the clinical problems of the population being served. Thus, a CM program for homeless people with AIDS has a much different mix of activities than a program serving patients with dementia and their caregivers, or one designed to improve the quality of diabetes care. Some CM interventions include primarily coordinating functions, while others focus mainly on clinical activities. Some target patients with characteristics – limited social support or physical or mental disability – that make them particularly vulnerable to lack of care coordination, while others serve unselected populations with a given chronic illness. Some interventions are intensive, with multiple face-to-face interactions and home visits, while others entail only infrequent telephone calls. In some, case managers operate independently, while in others, they work closely with a patient's usual care provider or with a multidisciplinary team of health professionals. The variability of CM interventions is a comparative effectiveness issue that will be addressed in this report. We will

examine the wide variety of CM approaches and define when and where CM leads to consistent effects on outcomes that are meaningful to patients and health care systems.

Objectives

We limited the scope of this review to CM interventions for medical, as opposed to psychiatric, illness. CM is often used to improve the management of psychiatric illnesses such as depression or schizophrenia, as well as substance use disorders. CM in those contexts, however, is substantively different in its nature and objectives from CM for chronic medical illness. Specifically this report summarizes the existing evidence addressing the following key questions:

Key Question 1:

In adults with chronic medical illness and complex care needs, is case management effective in improving:

- a. *Patient-centered outcomes*, including mortality, quality of life, disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care?
- b. *Quality of care*, as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior?
- c. *Resource utilization*, including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits)?

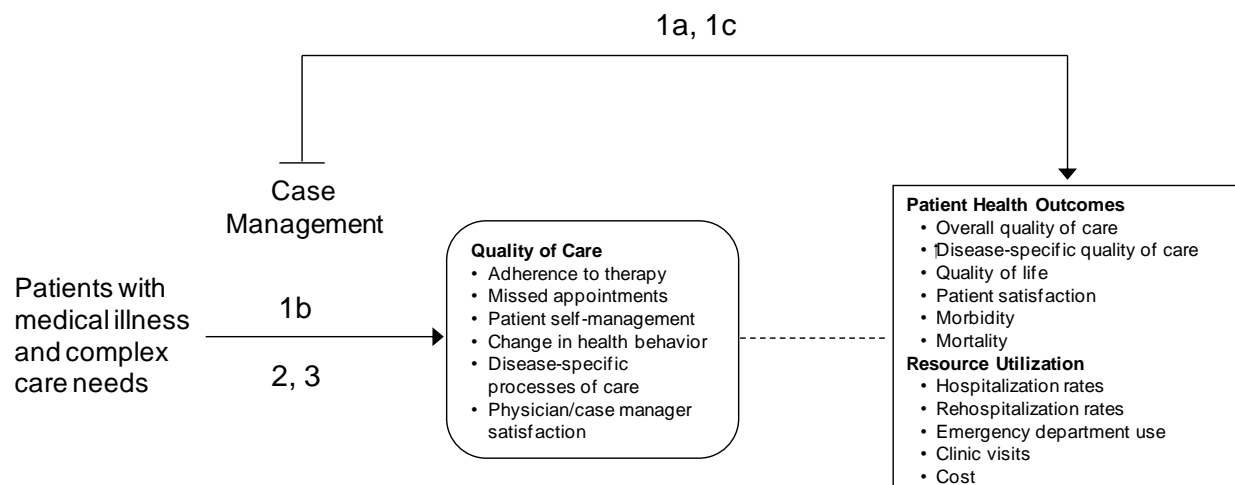
Key Question 2:

Does the effectiveness of case management differ according to *patient characteristics*, including but not limited to: particular medical conditions, number or type of comorbidities, patient age and socioeconomic status, social support, and/or level of formally assessed health risk?

Key Question 3:

Does the effectiveness of case management differ according to *intervention characteristics*, including but not limited to: practice or health care system setting; case manager experience, training, or skills; case management intensity, duration, and integration with other care providers; and the specific functions performed by case managers?

Figure A. Analytic Framework



Methods

Input from Stakeholders and Topic Refinement

Input from stakeholders was received during several phases of the project. In a topic refinement phase, the scope of the project was refined with input from a panel of Key Informants including representatives of public organizations and societies with an interest in CM, individuals who perform CM research, experts on the chronic care model, and practicing case managers. The key questions for the report were then revised and posted for public comments. A Technical Expert Panel (TEP) helped refine key questions, identify important issues, and define parameters for the review of evidence. Statements of potential conflicts of interest for all participants, researchers, and authors were reviewed by AHRQ.

Data Sources and Selection

Data sources included searches of the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials, EBM Reviews, CINAHL (EBSCO), and Ovid MEDLINE®. We searched broadly by combining terms for CM with terms for relevant research designs while limiting studies to those that focused on adults with medical illness(es) and complex care needs. Grey literature was identified by searching clinical trial registries (ClinicalTrials.gov, Current Controlled Trials, Clinical Trial Results, WHO Trial Registries), grants databases (NIHRePORTER, HSRProj, AHRQ GOLD), and individual funders' Web sites. Additional studies were identified by reviewing the reference lists of published clinical trials and review articles that addressed CM.

We developed criteria for inclusion and exclusion of studies based on the key questions and the populations, interventions, comparators, outcomes, timing, and setting (PICOTS) approach. The titles and abstracts for all citations initially were reviewed independently by two team members. Full-text articles were retrieved if one or both of the reviewers judged the citation to

be possibly relevant. The full-text articles then were reviewed independently by two team members for inclusion/exclusion. Disagreements were adjudicated by a third team member.

Populations of Interest

This review focuses on adults with medical illness and complex care needs. A main criterion in choosing studies for inclusion was the existence of complex care needs. Complex care needs were defined broadly, and we included studies with case definitions based on health care resource utilization, patient health status, and/or multi-factor assessments that included measures such as socio-economic status or patient self-efficacy. The included studies sometimes addressed populations in which psychiatric problems, such as depression, were important comorbid conditions. Studies of CM for dementia were included, because dementia is a clinical problem that often is managed in the primary care setting.

Studies in which the primary clinical problem was a psychiatric disorder (other than dementia) and in which CM was used primarily to manage mental illness or a substance abuse disorder were excluded. Although we did not include studies in which the goal of CM was primarily to improve psychiatric care, we did include studies in which CM was used to improve chronic medical illness care among patients who also had psychiatric illness.

Interventions

We define CM as a process in which a person (alone or in conjunction with a team) manages multiple aspects of a patient's care. Key components of CM include planning and assessment, coordination of services, patient education, and clinical monitoring. We excluded studies in which the case manager was a licensed independent practitioner, such as a primary care physician, a geriatrician, or a nurse practitioner. This is because such CM is part of the primary medical care provided to the patient rather than a separate clinical service.

Comparators

In most studies, CM is compared with usual care (i.e., care without a CM component). Usual care can be quite variable across studies and generally consisted of the array of services generally available to the population studied. When a study compared two or more different types of CM, then the comparator was the alternative type of CM. However, in most cases the comparator was the same milieu of clinical services without a distinct CM component. For clinical trials and other studies having a comparison group, we specifically examined the study's reports for information about contamination (provision of CM or other care coordination services to the control group).

Outcomes of Interest

The outcomes of interests are specified in the Key Questions listed above. The three categories of outcomes are patient-centered outcomes, quality of care outcomes, and resource utilization outcomes. These categories were derived from the set of outcomes specified in descriptions of CM programs in the literature. These programs address the needs of defined patient populations and have discrete clinical goals. These three categories reflect the categories of goals that usually are addressed in CM.

Comparative effectiveness reviews (CERs) commonly classify outcomes as either benefits or harms. The CM literature has not classified harms of CM. Thus, the outcomes listed above are

not classified as either benefits or harms. Thus, if a CM program led to an improvement in mortality, it could be considered a benefit. If it led to worse mortality, it could be considered a harm.

Timing

A level of longitudinal engagement with patients was a criterion for study inclusion. We excluded studies that provided CM for only short durations (30 days or less). This criterion excluded many studies that evaluated short-term post-hospitalization programs (often termed “transitional care” programs). Such programs fall into a large category of inpatient discharge planning activities that are beyond the scope of this review.

Settings

We included only studies in the outpatient setting, including primary care, specialty care, and home care settings. No geographic limitations were applied.

Types of Studies

We included randomized controlled trials and observational studies pertinent to the key questions. The observational studies included studies using quasi-experimental designs and studies having cohort, case-control and pre-post designs. Previously published systematic reviews were included if their definition of CM was consistent with that used in this project.

Evidence Synthesis

Data were abstracted and used to assess applicability and quality of the study: study design; inclusion and exclusion criteria; population and clinical characteristics (including sex, age, ethnicity, primary disease, comorbidities, complex care needs, and insurance carrier); CM intervention characteristics (including case manager professional identification and prior training); preintervention training for case managers; caseload and the nature of care provided by the intervention (e.g., patient education, coordination of services, medication monitoring, and adjustment); results for each outcome, focusing on the outcomes of interest (patient centered, resource utilization, and process of care outcomes). All study data were verified for accuracy and completeness and adjudicated by a second team member.

We used predefined criteria to assess the quality of individual controlled trials and observational studies adapted from methods proposed by Downs and Black (observational studies) and methods developed by the US Preventive Services Task Force. The criteria used are similar to those recommended by AHRQ in the draft Methods Reference Guide for Effectiveness and Comparative Effectiveness. Individual studies were rated as “good,” “fair,” or “poor.” Because of the broad range of models of CM, we grouped the studies by the types of program and the clinical problems that were chiefly addressed. For the majority of studies, these groupings were based on particular diagnoses, such as congestive heart failure (CHF), diabetes, or dementia, and studies of programs that addressed the needs of older adults with severe illness. We reviewed the findings of the studies for each of these categories and then assessed overall findings (across population groups), as related to the project’s key questions.

We used a qualitative approach to evidence synthesis. As mentioned above, the comparator in nearly all the clinical trials was “usual care” that could not be well quantified. Thus, we felt that statistical pooling of results and formal meta-analyses would not be valid.

The strength of evidence for each key question was initially assessed for the outcomes applicable to each patient category. We used the approach described by Owens, et al.⁶ to evaluate the body of evidence for each outcome in each patient category. This approach uses the following categories:

- Risk of bias (low, medium, or high)
- Consistency (consistent, inconsistent, or unknown/not applicable)
- Directness (direct or indirect)
- Precision (precise or imprecise)

We also estimated publication bias by examining whether studies with smaller sample size tended to have positive or negative assessments of CM effectiveness. Applicability was estimated by examining the characteristics of the patient populations and clinical settings in which the studies were performed. The strength of evidence was assigned an overall grade of High, Moderate, Low, or Insufficient according to a four-level scale.

Results

Overall, the multiple search sources yielded 4789 citations, of which 823 full-text articles were retrieved. A total of 99 articles were judged to be relevant. Due to multiple publications for some studies, there were 76 total studies. The majority were randomized controlled trials. The studies were sorted by patient population and were assigned to the following categories:

- Cancer (6 studies)
- Chronic disease in older adults (11 studies)
- Chronic infections (HIV or TB) (12 studies)
- Congestive heart failure (10 studies)
- Diabetes mellitus (10 studies)
- Dementia (12 studies)
- Frail elderly (8 studies)
- Miscellaneous patient populations (7 studies)

The specific outcomes reported in studies varied across the population groups, particularly for the patient-centered outcomes (Key Question 1a). Thus, the conclusions drawn from the evidence syntheses often are specific to the individual patient populations. These population-specific conclusions are summarized in Table A below.

The sample sizes of the studies of CM were variable, but many of the studies included fairly small samples of patients. Thus, for most studies sub-group analyses were not possible. For Key Question 2, the population comparisons were based on indirect comparisons from separate studies.

Nearly all of the clinical trials of CM programs compared a single type of program to a usual care condition. There were very few trials that directly compared more than one model of CM. This limited the evidence available for Key Question 3. Another limitation was that many studies included incomplete information about the content of the CM that was delivered to patients.

Due to heterogeneity in the characteristics of CM interventions and the limitation of small sample sizes in many studies, the strength of evidence for the conclusions often is only low or moderate. This applies to statements about both positive effects and the lack of effect on outcomes. However, in some cases there were consistent findings in large clinical trials of uniform populations. In such cases, the evidence statements were assigned high strength of evidence ratings.

Key Question 1a. In adults with chronic medical illness and complex care needs, is case management effective in improving *patient-centered outcomes*?

Mortality. Patients provided CM did not experience lower mortality in general populations of patients with chronic illness, in the frail elderly, those with AIDS, or in patients with terminal cancer.

Quality of life and functional status. CM interventions produced mixed results in terms of improving patients' quality of life (QOL) and functional status. In general, CM was frequently successful in improving aspects of functioning and QOL that were directly targeted by the interventions. For instance, CM was successful in improving caregiver stress among persons caring for patients with dementia and CHF-related QOL among patients with CHF. The measures used to evaluate QOL and functional status varied across studies, and overall, the improvements in QOL and functional status achieved by CM were either small or of unclear clinical significance. CM was less successful in improving overall quality of life and functioning, as indicated by global measures not specific to a particular condition.

Ability to remain at home. One measure of the clinical significance of improvements in functioning for elderly patients with chronic conditions is the ability to remain at home and avoid nursing home placement. This outcome was often the primary objective of CM programs for patients with dementia. In most studies, CM was not effective in maintaining patients' ability to live at home. Evidence from one study suggests that a high-intensity CM intervention sustained over a period of several years can produce a substantial delay in nursing home placement for patients with dementia.

Disease-specific health outcomes. The effect of CM on disease-specific outcomes was inconsistent. In some studies, CM had a positive impact on specific symptoms, including pain and fatigue in patients with cancer and depressive symptoms among caregivers of patients with dementia. Notably, however, CM did not have a significant impact on clinical outcomes among patients with diabetes, including glycohemoglobin levels, blood pressure, and lipids.

Patient satisfaction with care. CM interventions were generally associated with improved patient (and caregiver) satisfaction, although satisfaction with CM varied across interventions. Studies measuring patient satisfaction typically reported overall satisfaction with care, rather than satisfaction in specific domains. Some interventions improved patient satisfaction across multiple domains of patients' experience with care, while others did not improve satisfaction in

any measured domain. Satisfaction was most substantially improved in the domain of coordination among health care providers.

Key Question 1b. In adults with chronic medical illness and complex care needs, is case management effective in improving *quality of care*?

Disease-specific process measures and receipt of recommended services. CM was effective in increasing the receipt of recommended health care services when it was an explicit objective of the CM intervention. For instance, CM interventions designed to improve cancer therapy for patients with breast and lung cancer were successful in increasing the receipt of radiation treatment, as recommended in clinical guidelines. The effect of CM on guideline-recommended care in general, however, was less consistent. Studies showed only sporadic effects on elements of quality of care, such as receipt of appropriate medications for patients with CHF or diabetes, or receipt of appropriate preventive services for elderly patients. There was no clearly discernible pattern indicating which features of CM interventions were successful in improving patients' receipt of appropriate services.

Patient self-management. CM was effective in improving patients' self-management behaviors, including dietary and medication adherence, for specific conditions such as CHF or tuberculosis, when patient education and self-management support were included within CM interventions.

Missed appointments. Few studies measured the frequency of missed appointments as an outcome of CM interventions.

Key Question 1c. In adults with chronic medical illness and complex care needs, is case management effective in improving *resource utilization*?

Hospitalization rates. Among hospitalized patients at high risk for readmission, CM reduced rehospitalization rates. This effect was most notable among patients with CHF, which is the leading cause of hospitalization in elderly patients. For broader groups of patients with chronic disease, CM did not reduce hospitalization rates in general.

Emergency department use. The effect of CM on emergency department (ED) use was varied. Several studies found reduced ED use in patients receiving CM, but other studies found no effect.

Clinic visits. Few studies measured the frequency of clinic visits as an outcome of CM interventions. Those that did generally showed increases in numbers of outpatient visits.

Overall expenditures. Most studies examining the impact of CM on the overall cost of care showed no significant difference between CM and control groups. For patient populations with high rates of hospitalization (e.g., CHF), CM interventions that substantially reduced

hospitalization rates tended to reduce costs as well, since hospitalization was usually the most significant source of health care expenditure.

Key Question 2: Does the effectiveness of case management differ according to *patient characteristics*?

Medical conditions. Individual studies had inconsistent findings on whether CM interventions are more successful for patients with high disease burden. While it is possible that there is a mid-range of disease burden in which CM is most effective, the evidence base does not permit defining how to identify such patients.

Age. Most studies of CM included mainly elderly patients, making it difficult to determine impact of age on CM effectiveness.

Socioeconomic status. Studies did not routinely report the effect of CM according to socioeconomic indicators among enrolled patients. Some studies explicitly targeted low-income or homeless populations. There was no apparent pattern to suggest an influence of patients' socioeconomic status on the effectiveness of CM.

Social support. Few studies explicitly evaluated patients' level of social support. In studies that evaluated CM effectiveness in patients with differing levels of social support, CM appeared to be most effective in patients with limited social support, as indicated by being unmarried or living alone. An exception is patients with dementia for which the goal is keeping the patient living at home. In this case higher social support (a spouse caregiver) was associated with longer success in staying at home.

Formally assessed health risk. Some studies explicitly targeted patients considered to be at high risk of poor outcomes. The methods used to evaluate risk, however, varied substantially across studies. In general, CM was most effective in patients judged to be at high risk. This was particularly true for the impact of CM on hospitalization rates. Patients who were hospitalized at enrollment (and thereby known to be at risk for re-hospitalization), and patients with clinical risk factors for readmission, tended to benefit most from CM.

Key Question 3. Does the effectiveness of case management differ according to *intervention characteristics*?

Setting. CM interventions implemented prior to discharge from a hospital were sometimes successful in preventing readmission. Other characteristics of the setting in which CM were implemented (e.g., integrated health system, home health agency, outpatient clinic) did not clearly influence the effectiveness of CM.

Case manager experience, training, skills. Studies did not consistently provide details about the experience, training, or skills of case managers. In most studies the case managers were nurses, and some had specialized training in caring for patients with the conditions targeted by the CM intervention (e.g., diabetes, cancer, dementia). There was some evidence that pre-intervention

training of nurses in providing CM for the targeted conditions, the use of protocols or scripts to guide clinical management, and collaboration between a case manager and a physician (or multidisciplinary team) specializing in the targeted clinical condition, resulted in more successful interventions.

Case management intensity, duration, integration with other care providers. Studies across multiple patient groups suggested that more intense CM interventions, as indicated by greater contact time, longer duration, and face-to-face (as opposed to only telephone) visits, produced better outcomes, including functional outcomes and lower hospitalization rates. In addition, CM interventions that were more tightly integrated with patients' usual care providers (typically primary care physicians) tended to produce, on balance, better results. The most successful interventions generally had more contacts between case managers and patients and were more integrated with the hospitals and physicians where patients received care.

Table A. Summary evidence table: Comparative effectiveness of case management for adults with medical illness and complex care needs

Key Question	Condition/ Disease	Strength of Evidence	Conclusion
Key Question 1a: In adults with chronic medical illness and complex care needs, is case management effective in improving <i>patient-centered outcomes</i> , including mortality, quality of life, disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care?	Multiple chronic diseases in older adults	High	<i>Mortality.</i> CM programs that serve patients with multiple chronic diseases do not reduce overall mortality.
		High	<i>Functional status.</i> CM programs that serve patients with multiple chronic diseases do not result in clinically important improvements in functional status.
	Frail elderly	Low	<i>Mortality.</i> CM does not affect mortality in frail elders.
	Dementia	Moderate	<i>Depression and strain.</i> CM programs that serve patients with dementia reduce depression and strain among caregivers.
		Moderate	<i>Time to nursing home placement.</i> CM programs that serve patients with dementia and have duration of no longer than two years do not confer clinically important delays in time to nursing home placement.
	Diabetes	Moderate	<i>Glucose management.</i> CM programs that serve diabetic adults do not improve glucose management.
		Moderate	<i>Lipids, blood pressure, BMI/weight.</i> CM programs that serve diabetic adults do not improve measures of lipid management, blood pressure management, or BMI/weight.

Key Question	Condition/ Disease	Strength of Evidence	Conclusion
		Low	<i>Mortality.</i> CM programs that serve adults with diabetes do not reduce mortality.
		Low	<i>Quality of life.</i> CM programs that serve diabetic adults do not improve quality of life.
	Cancer	Moderate	<i>Satisfaction with care.</i> CM programs that serve patients with cancer improve satisfaction with care.
		Low	<i>Cancer-related symptoms, functioning, quality of life, survival.</i> CM improves selected cancer-related symptoms and functioning (physical, psychosocial, and emotional) but not overall quality of life or survival.
	CHF	Moderate	<i>Patient satisfaction.</i> CM programs that serve patients with CHF increase patient satisfaction.
		Low	<i>Quality of life.</i> CM programs that serve patients with CHF improve CHF-related quality of life.
	HIV	Low	<i>Survival.</i> CM programs that serve adults with HIV infection do not improve survival.
	Other chronic conditions	Low	<i>Cardiac risk factors.</i> Case management programs that focus on cardiac risk factors result in small improvements in these risk factors
Key Question 1b: In adults with chronic medical illness and complex care needs, is case management effective in improving <i>quality of care</i> , as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior?	Multiple chronic diseases	Moderate	<i>Patient perception of care coordination.</i> CM programs that serve patients with multiple chronic diseases increase patients' perceptions of the coordination of their care.
	Dementia	Low	<i>Clinical guideline adherence.</i> CM programs that focus on clinical guideline measures for care of dementia increase adherence to those measures.
	Diabetes	Low	<i>Medication and screening adherence.</i> CM programs that serve diabetic adults improve medication adherence and adherence to recommended screening tests.

Key Question	Condition/ Disease	Strength of Evidence	Conclusion
	Cancer	Moderate	<i>Appropriate treatment.</i> CM programs that serve patients with cancer increase the receipt of appropriate (i.e., guideline-recommended) cancer treatment.
	CHF	Moderate	<i>Self-management behaviors.</i> CM increases patients' adherence to self-management behaviors recommended for patients with CHF.
	TB	Moderate	<i>Treatment success.</i> Short-term CM programs that emphasize medication adherence improve rates of successful treatment for tuberculosis in vulnerable populations.
Key Question 1c: In adults with chronic medical illness and complex care needs, is case management effective in improving <i>resource utilization</i> , including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits)?	Multiple chronic diseases	High	<i>Medicare expenditures.</i> CM programs that serve patients with multiple chronic diseases do not reduce Medicare expenditures.
		Moderate	<i>Hospitalization rates.</i> CM programs that serve patients with multiple chronic diseases do not reduce overall rates of hospitalization.
	Frail elderly	Low	<i>Hospitalization rates.</i> CM does not decrease acute hospitalizations in the frail elderly.
	Dementia	Moderate	<i>Health care expenditures.</i> CM does not reduce health care expenditures for patients with dementia.
		Moderate	<i>Physician visits.</i> CM does not reduce the use of physician visits for patients with dementia.
		Low	<i>Hospitalization rates.</i> CM does not increase acute care hospitalizations rates for patients with dementia.
	Diabetes	Low	<i>Resource utilization.</i> CM programs that serve diabetic adults do not improve resource utilization.
	Cancer	Low	<i>Health care utilization, cost of care.</i> CM programs that serve patients with cancer have little effect on overall health care utilization and cost of care.
	CHF	Low	<i>Hospital readmission rates.</i> CM reduces readmission rates among hospitalized CHF patients at high risk for readmission.

Key Question	Condition/ Disease	Strength of Evidence	Conclusion
	Other clinical conditions	Low	<i>Emergency department visits.</i> Case management programs that serve homeless or uninsured patients reduce emergency department visits.
Key Question 2: Does the effectiveness of case management differ according to <i>patient characteristics</i> , including but not limited to: particular medical conditions, number or type of comorbidities, patient age and socioeconomic status, social support, and/or level of formally assessed health risk?	Multiple chronic diseases	Low	<i>Disease burden.</i> CM programs that serve patients with multiple chronic diseases are more effective for reducing hospitalization rates among patients with greater disease burden.
	Diabetes	Low	<i>Race, ethnicity, type of diabetes.</i> CM is not more effective at improving health outcomes among particular racial and ethnic sub-groups.
	Cancer	Low	<i>Level of social support.</i> CM programs that serve patients with cancer are more effective when targeted to cancer patients with lower levels of social support.
Key Question 3: Does the effectiveness of case management differ according to <i>intervention characteristics</i> , including but not limited to: practice or health care system setting; case manager experience, training, or skills; case management intensity, duration, and integration with other care providers; and the specific functions performed by case managers?	Multiple chronic diseases	Moderate	<i>Personal contact.</i> CM programs that serve patients with multiple chronic diseases are more effective for preventing hospitalizations when case managers have greater personal contact with patients and physicians.
	Dementia	Low	<i>Duration.</i> CM programs that serve patients with dementia who have in-home spouse caregivers and continue services for longer than two years are more effective for delaying nursing home placement than programs providing services for 2 years or less.
	Cancer	Low	<i>Intensity, integration, training, protocols.</i> CM programs that serve patients with cancer are more effective when the CM is more intensive, better integrated with patients' usual care providers, and employs preintervention training and care protocols.
	CHF	Low	<i>Multidisciplinary team.</i> CM is more effective in improving outcomes among CHF patients when case managers are part of a multidisciplinary team of health care providers.

Key Question	Condition/ Disease	Strength of Evidence	Conclusion
	TB and HIV	Low	<i>Visit frequency.</i> More frequent visits by a case manager are associated with higher rates of clinical improvement in HIV and TB infections.

Abbreviations: CM, case management; BMI, body mass index; CHF, congestive heart failure; HIV, human immunodeficiency virus, TB, tuberculosis.

Discussion

CM is a strategy for improving the delivery of clinical services to patients with complex needs. The types of patient who potentially could benefit from CM fall into four distinct categories:

- Patients who have serious chronic diseases that are progressive and life-threatening but can be improved with proper treatment, such as CHF or HIV infection.
- Patients with progressive debilitating and often irreversible diseases for which supportive care can enhance independence and quality of life, such as dementia or multiple chronic diseases in the aged.
- Patients who have progressive chronic diseases for which self-management can improve health and functioning, such as diabetes mellitus.
- Patients for whom serious social problems impair their ability to manage disease, such as the homeless.

For all of these clinical categories health care resources generally are available but may be inaccessible or poorly coordinated. Case managers can help to surmount these problems, but the role of the case manager is complex. Depending on the organization and strategy of CM programs, the case manager can play distinctly different roles:

- A care provider who helps patients improve their self-management skills and/or helps caregivers to be more effective in helping and supporting patients.
- A collaborative member of the care delivery team who promotes better communication with providers and advocates for implementation of care plans.
- A patient advocate who evaluates patient needs and works to surmount problems with access to clinical services.

There are multiple strategies for fulfilling these roles, and CM programs are consequently complex and often difficult to replicate. Organizationally, programs can be free-standing or imbedded in clinical settings (usually primary care or specialty practices). Case managers can interact with patients in their homes, in clinics, or by telephone. Case managers can have caseloads of hundreds or only a few dozen. Case managers can follow pre-specified protocols or can develop personalized care plans based on patient assessments. Case managers can work independently or can function as a member of a CM team. The studies of CM use a variety of approaches to describe their programs, and full specification of the program's content often is not possible. Acknowledging this heterogeneity of study populations, interventions, and outcomes, we sought to discern the conditions under which CM was effective or ineffective.

There is a substantial evidence base about CM for complex chronic diseases. More than 50 randomized controlled trials have been conducted in a variety of patient populations, and a smaller number of good-quality non-experimental studies also have been reported. The total number of participants in these studies approaches 100,000. The majority of these studies have given good descriptions of the patient populations, making it possible to organize the evidence by population groups. In some cases, there has been enough similarity in patient populations that indirect comparisons of different types of programs can be made with moderate confidence.

The cumulative evidence about CM is sufficient to draw several conclusions, some of which pertain to the inability of CM programs (as they have been commonly deployed) to achieve some desired outcomes. Generally, the conclusions reached in this report pertain only to specific patient populations. Because CM programs generally are customized to the patient groups served, it usually is not possible to apply the results to other patient populations. In this review, we found that, on balance, CM had limited impact on patient-centered outcomes, quality of care, and resource utilization among patients with chronic medical illness. The most positive findings are that CM improves the quality of care, particularly for patients with serious illnesses that require complex treatments (cancer and HIV). For a variety of medical conditions, CM improves medication adherence and self-management skills. CM also improves quality of life in some populations (CHF and cancer) and tends to improve satisfaction with care. For the caregivers of patients with dementia, targeted CM programs improve levels of stress, burden, and depression.

We found low-level evidence that CM is effective in improving resource utilization (particularly lower hospitalization rates) only for patients with CHF or those with chronic homelessness. In most other cases, CM programs have not demonstrated cost savings. For patients who receive CM for multiple chronic diseases, there is high-level evidence that the programs do not reduce Medicare expenditures. While the effectiveness of CM may depend on selection of the appropriate target population, the published studies suggest that this type of careful case selection is difficult to implement.

The results of trials across different clinical conditions suggest that CM effectiveness was greater when the intervention was more prolonged, included more patient contact, and included face-to-face (rather than telephone only) interactions. This finding validates the premise that the relationship between case manager and patient is likely to be a key ingredient for successful CM interventions. CM also appears to be most effective when the case manager works closely with patients' usual care providers (usually primary care physicians) and/or collaborates with a physician (or multidisciplinary team of health care providers) with expertise in managing the targeted medical condition. This finding suggests that CM may be most effective when case managers are embedded within a collaborative, team-based intervention model. Finally, there also is some evidence that CM is successful in achieving outcomes when the intervention includes specific training modules and protocols that are tailored towards those outcomes. This suggests that the breadth and flexibility of CM may need to be complemented by focused efforts – including specific training, guidelines, and protocols – to achieve explicitly targeted outcomes.

Implications for Future Research

The existing evidence base includes a large number of randomized controlled trials comparing CM to “usual care.” In some cases (particularly the Medicare Coordinated Care Demonstration [MCCD] trial)⁷ the studies had large sample sizes and good overall methodological quality. The results of such evaluations are relatively clear, and there is a

relatively low yield in continuing to repeat such studies. Instead, future clinical research needs to address the gaps in the current evidence base. These gaps include:

- Lack of effective risk assessment tools for choosing candidates for CM. Some published trials⁸ have used existing tools, but no studies have compared tools or rigorously examined patient sub-groups to learn which patients achieve the greatest benefits from CM. The factors included in better risk profiles could include:
 - Demographics including age, gender, and ethnicity
 - Indicators of socioeconomic status and access to health care
 - Measures of social support
 - Health care utilization profiles
 - Clinical risk factors for adverse outcomes
- Lack of understanding of the length of time to continue CM. Nearly all trials have set seemingly arbitrary durations of the intervention (often 1-2 years). It is not known when the benefits of the intervention have been achieved. Some of the negative results may be due to the CM being too short. This is particularly important if developing an effective long-term relationship between the patient and case manager affects the program's success.
- Imprecision about the intensity of CM. Existing trials have infrequently examined whether patient outcomes are influenced by the frequency of case manager contact, the length and content of the contacts, and the approach to follow up of problems.

Glossary

Case management (CM): A health care service in which a single person, working alone or in conjunction with a team, coordinates services and augments clinical care for patients with chronic illness.

References

1. Institute of Medicine. Crossing the quality chasm: A new health system for the 21st century. Washington DC: The National Academies Press; 2001.
2. Boulton C, Kane RL, Pacala JT, Wagner EH. Innovative healthcare for chronically ill older persons: results of a national survey. *American Journal of Managed Care*. Vol 5; 1999;1162-1172.
3. Kane RL. What Can Improve Chronic Disease Care? *Journal of the American Geriatrics Society*. 2009;57(12):2338-2345.
4. McDonald KM, et al. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies (Vol. 7: Care Coordination). In: Shojania KG MK, Wachter RM, Owens DK, editors, ed. Vol AHRQ Publication No. 04(07)-0051-7: Agency for Health Care Research and Quality: Rockville, MD; 2007.
5. Krumholz HM, Currie PM, Riegel B, et al. A taxonomy for disease management: a scientific statement from the American Heart Association Disease Management Taxonomy Writing Group. *Circulation*. Sep 26 2006;114(13):1432-1445.
6. Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions--agency for healthcare research and quality and the effective health-care program. *J Clin Epidemiol*. May 2010;63(5):513-523.
7. Peikes D, Chen A, Schore J, Brown R. Effects of Care Coordination on Hospitalization, Quality of Care, and Health Care Expenditures Among Medicare Beneficiaries. *JAMA: The Journal of the American Medical Association*. February 11, 2009 2009;301(6):603-618.
8. Boulton C, Reider L, Leff B, et al. The effect of guided care teams on the use of health services: results from a cluster-randomized controlled trial. *Arch Intern Med*. Mar 14 2011;171(5):460-466.

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Introduction

Background

Chronic diseases are the leading cause of illness, disability, and death in the United States.¹ Nearly half of all adults in the United States have at least one chronic disease, and 43 percent of adults covered by both Parts A and B of Medicare have three or more chronic diseases.² Providing medical care for chronic illness is often complex. Patients require multiple resources, treatments, and providers that, in many United States health care settings, are not integrated into a coherent system of care but rather function as separate entities that must be coordinated to meet an individual patient's needs. This fragmentation puts patients with serious or multiple chronic illnesses at risk of experiencing inadequate quality of care and makes their health care expenditures substantially higher than for those who have minor or no chronic conditions.³

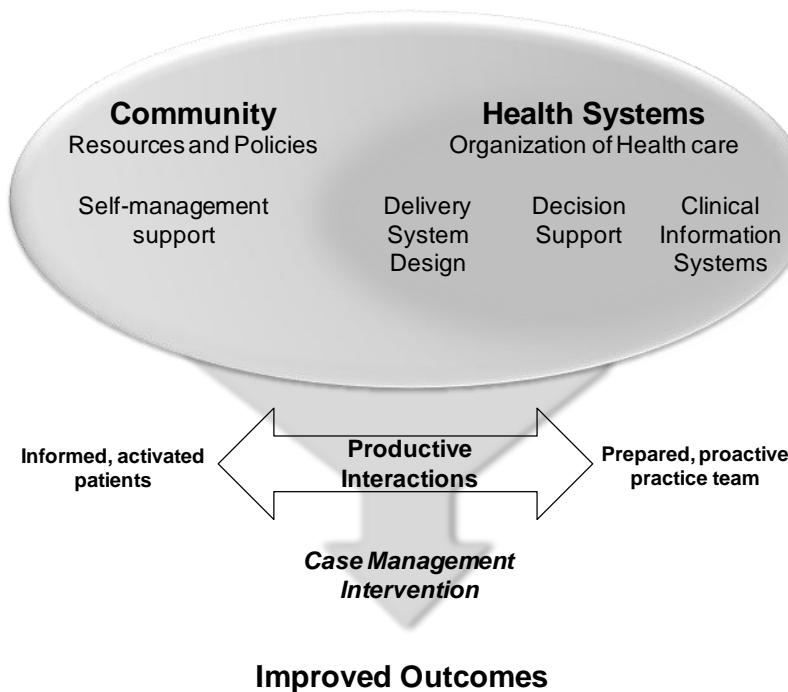
A strategy to improve the coordination and efficiency of care for chronic conditions is to add supplemental services and personnel to improve care coordination and implement care plans.⁴⁻⁶ Case management (CM) is one such supplemental service, in which a single person, usually a nurse or social worker, takes responsibility for coordinating and implementing a patient's care plan, either alone or in conjunction with a team of health professionals. Early models of CM were developed as part of the community health nursing movement of the early twentieth century. They were designed largely to promote patient self-help and coordinate community resources.⁷ A central feature of these models was that the nurse case manager had roles in both coordinating services and providing clinical care directly.⁸ In the 1970s CM was widely used to meet the needs of patients with chronic psychiatric diseases.⁹⁻¹¹ In the AIDS epidemic of the 1980s, CM was adopted to coordinate treatment programs for human immunodeficiency virus (HIV)-infected individuals. At about the same time, a model of CM for the frail elderly began to be disseminated.¹²

The evolution of CM models in health care, and their expanding use in chronic illness management, has led to the term "case management" being used to describe a wide variety of interventions. As a result, there is no consensus as to what constitutes CM. Moreover, the term "case management" is often used interchangeably with other forms of chronic illness management interventions – such as "disease management," and "self-management support" – and the health professionals administering those programs, usually nurses, are often referred to as case managers. The conflation of these different terms – and their unsystematic use in describing nurse-led, chronic illness management interventions – makes it challenging to examine the contribution of CM as a distinct entity. For example, McDonald, et al. recently reviewed 75 systematic reviews of studies evaluating the effectiveness of care coordination strategies for patients with chronic illness.⁶ Many of these strategies were nurse-led interventions for patients with diabetes, congestive heart failure (CHF), and other chronic conditions, and 21 of the systematic reviews reported evaluating CM as an explicit objective. Most of these systematic reviews included studies of interventions that carried the label "case management" did not typically define CM or distinguish it from other nurse-led interventions. Most of these reviews also did not isolate the effects of CM from other clinical interventions.⁶

Distinguishing Case Management from Other Interventions

We sought to add to the existing body of evidence on chronic illness management interventions by evaluating the distinct contribution of CM as a specific strategy. CM tends to be more intensive in time and resources than other chronic illness management interventions, and it is therefore important to evaluate the specific value of this intense use of resources. To distinguish CM from other interventions, we drew upon definitions of CM in the literature and those used by professional organizations of case managers (see Appendix A). We also consulted with members of our Technical Expert Panel (TEP) who are experts in the field of CM. Those definitions and expert opinions indicated that a defining feature of CM is the central role of the manager as comprehensive coordinator of a patient's care. For instance, McDonald, et al. defined CM as involving the "assignment of a single person who coordinates all aspects of a patient's care."⁶ The coordinating functions performed by a case manager included helping patients navigate health care systems, connecting them with community resources, orchestrating multiple facets of health care delivery, and assisting with administrative and logistical tasks. These *coordinating* functions are distinct from *clinical* functions, including disease-oriented assessment and monitoring, medication adjustment, health education, and self-care instructions. Such clinical functions are often the defining aspects of other chronic illness management interventions. In the context of chronic illness care, they are central to the role of a case manager as well, but a case manager also performs coordinating functions. The role of case managers in chronic illness care, and their distinction from other professionals involved in chronic illness management support, can be illustrated using the Chronic Care Model (see Figure 1).

Figure 1. Adapted chronic care model



Adapted from The MacColl Institute

Many chronic illness management interventions include professionals (usually nurses) who are members of a clinical practice team or perform discrete clinical functions (e.g., clinical monitoring and education) on behalf of the practice team. A case manager also performs these functions, but a central role of the case manager is to coordinate and integrate different types of services, including community resources, health systems, and the practice team, on behalf of the patient. CM is often utilized when such coordination and integration are inherently challenging and difficult for patients to accomplish on their own. CM usually involves high-intensity engagement with such patients, and case managers often adopt a supervisory role in comprehensively attending to patients' complex needs.¹³ Conceptually, a case manager can be seen as an agent of the patient, taking a "whole-person" (rather than solely clinical or disease-focused) approach to care, and serving as a bridge between the patient, the practice team, the health system, and community resources (Table 1).

Table 1. Features of case management programs

Features shared with other chronic illness management programs
<ul style="list-style-type: none"> • Clinical assessment • Care planning • Health education • Self care instructions • Monitoring clinical parameters • Adjusting medications • Communicating with practice team
Distinctive features of case management
<ul style="list-style-type: none"> • Prominent supervisory role in coordinating multiple aspects of care • High-intensity, longitudinal engagement with patient (and families or other caregivers) • Functioning as patient advocate/agent • Comprehensively assessing, monitoring, and addressing patients' needs (e.g., physical, psychological, social, emotional) • Facilitating access to community resources, including social services • Mainly for patients with complex care needs

Not all chronic illness management interventions that include clinical and coordinating activities are CM. A defining aspect of CM is that it involves a single person or small group of persons (i.e., case managers) who are responsible for those activities. Other chronic illness management interventions – including "multidisciplinary teams" and "organized specialty clinics"⁶ – may include clinical and coordinating activities as part of their overall approach to care, but such team-based interventions are distinct from CM.

Another feature of CM is the level and duration of engagement with patients. Some chronic illness management interventions, particularly those designed to smooth transitions of care, include clinical and coordinating functions but are limited to one or two encounters with the patient. CM involves longitudinal engagement with patients, allowing for the development of a case manager-patient relationship.

Finally, CM is a supplemental intervention that occurs in addition to (and often in conjunction with) "usual" clinical care. A primary care or specialist practitioner caring for a patient may perform both clinical and coordinating activities, may be the principal person responsible for those functions, and may have a longitudinal relationship with the patient. But these "usual care" practitioners (e.g., primary care practitioners) are not considered case managers.

Variability of Case Management Implementation

Even when CM is defined explicitly – as a longitudinal intervention in which a single person, working alone or in conjunction with a team, coordinates services and augments clinical care for patients with chronic illness – there is wide variation in its implementation. Individual CM programs usually are customized for the clinical problems of the population being served. Thus, a CM program for homeless people with AIDS has a much different mix of activities than a program serving patients with dementia and their caregivers, or one designed to improve the quality of diabetes care. Some CM interventions include primarily coordinating functions, while others focus mainly on clinical activities. Some target patients with characteristics – limited social support or physical or mental disability – that make them particularly vulnerable to lack of care coordination, while others serve unselected populations with a given chronic illness. Some interventions are intensive, with multiple face-to-face interactions and home visits, while others entail only infrequent telephone calls. In some, case managers operate independently, while in others, they work closely with a patient’s usual care provider or with a multidisciplinary team of health professionals. This variability of CM interventions makes it challenging to evaluate the effectiveness of CM as a discrete entity. It is therefore of potentially greater interest to evaluate the impact of specific components within CM intervention “packages.” However, in many studies, the way in which CM is implemented is poorly described, making it difficult to study the individual components of CM interventions.

Scope and Key Questions

The Agency for Healthcare Research and Quality (AHRQ) commissioned this Comparative Effectiveness Review (CER) to examine the evidence for the effectiveness of CM programs for chronic illness patients with complex care needs. To define the scope of the review, we used the framework described above to define CM interventions. Specifically, we considered interventions in which case managers had a substantive role in performing both clinical and coordinating functions. Although some interventions may include coordinating functions without explicitly describing them, we only included interventions in this review for which those functions were central enough to the manager’s role to be described as part of the intervention. Because the balance of clinical and coordinating activities varies widely across CM interventions, our review included a diverse array of interventions in which case manager roles spanned a continuum, from predominantly clinical to predominantly coordinating in nature.¹⁴ We used the description of the intervention and its components, rather than its label, to make decisions about which interventions had the defining characteristics of CM as described above. Thus, we did not include all interventions that were labeled in the literature as CM, and we sometimes included interventions carrying other labels (including care management and disease management).

We limited the scope of this review to CM interventions for medical, as opposed to psychiatric, illness. CM is often used to improve the management of psychiatric illnesses such as depression or schizophrenia, as well as substance use disorders. CM in those contexts, however, is substantively different in its nature and objectives from CM for chronic medical illness. Although we did not include studies in which the goal of CM was primarily to improve psychiatric care, we did include studies in which CM was used to improve chronic medical illness care among patients who also had psychiatric illness.

Key Question 1:

In adults with chronic medical illness and complex care needs, is case management effective in improving:

- d. *Patient-centered outcomes*, including mortality, quality of life (Q), disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care?
- e. *Quality of care*, as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior?
- f. *Resource utilization*, including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits)?

Key Question 2:

Does the effectiveness of case management differ according to *patient characteristics*, including but not limited to: particular medical conditions, number or type of comorbidities, patient age and socioeconomic status, social support, and/or level of formally assessed health risk?

Key Question 3:

Does the effectiveness of case management differ according to *intervention characteristics*, including but not limited to: practice or health care system setting; case manager experience, training, or skills; case management intensity, duration, and integration with other care providers; and the specific functions performed by case managers?

Methods

Topic Development and Refinement

The original topic nomination was submitted to the Agency for Healthcare Research and Quality (AHRQ) by a member of the general public. It proposed a comparative effectiveness review of case management (CM) (performed by certified nurse case managers) for improving utilization and costs of health services. The original nomination specified a broad population of interest (“all patients”) and did not further specify the outcomes of interest. Because a literature scan identified diverse populations, interventions, and outcomes, the nomination was further scoped during topic refinement to produce more specific key questions.

The AHRQ Task Order Officer (TOO) was responsible for overseeing all aspects of this project. The TOO facilitated a common understanding among all parties involved in the project, resolved ambiguities, and advised on the scope and processes of the project. The TOO and other staff at AHRQ reviewed the report for consistency, clarity, and to ensure that it conformed to AHRQ standards.

During a topic refinement phase, the scope of the project was refined with input from a panel of Key Informants. Key Informants included representatives of public organizations and societies with an interest in CM, individuals who have performed CM research, experts on the chronic care model, and practicing case managers. The key questions for the report were then revised and posted for public comments. A Technical Expert Panel (TEP) was then formed to help refine key questions, identify important issues, and define parameters for the review of evidence. Discussions among the project investigators, Evidence-based Practice Center (EPC), TOO, Key Informants, and the TEP occurred during a series of teleconferences and via email. In addition, input from the TEP was sought during compilation of the report when questions arose about the scope of the review.

Three key questions are addressed in the present report. One pertains to outcomes in patients and caregivers who receive services from case managers (Key Question 1), one addresses associations between patient factors and the results of CM (Key Question 2), and one addresses comparison among different types and models of CM (Key Question 3).

Search Strategy

To identify articles relevant to each key question, we searched the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials, EBM Reviews, CINAHL (EBSCO), and Ovid MEDLINE®. We searched broadly by combining terms for CM with terms for relevant research designs while limiting studies to those that focused on adults with medical illness(es) and complex care needs (see Appendix B for search strings). Grey literature was identified by searching clinical trial registries (ClinicalTrials.gov, Current Controlled Trials, Clinical Trial Results, WHO Trial Registries), grants databases (NIHRePORTER, HSRProj, AHRQ GOLD), and individual funders' Web sites. Additional studies were also identified by reviewing the reference list of published clinical trials and review articles that addressed CM.

The searches found a total of 4789 citations. All citations were imported into an electronic database, EndNote® X3.

Study Selection

We developed criteria for inclusion and exclusion of studies based on the key questions and the populations, interventions, comparators, outcomes, timing, and setting (PICOTS) approach (see Appendix C). To reduce bias and enhance consistency in our study selection process, we initially had three reviewers review 100 citations for inclusion and calculated kappa values to estimate inter-reviewer reliability. After discussing and reconciling disagreements between reviewers, the same three team members reviewed an additional 100 citations. We continued this process until the kappa values reached >0.50 for each pair of reviewers. Two reviewers then reviewed each title and abstract for inclusion and exclusion, using our preestablished inclusion/exclusion criteria to determine potential eligibility for inclusion in the evidence synthesis. All citations judged to be possibly included by one or both of the reviewers were retrieved as full-text articles.

Each full-text article was reviewed independently by two team members. If there was consensus between the two, then the article was either included or excluded. In cases of disagreement, a senior investigator reviewed the article and made the decision on inclusion/exclusion. A data file of excluded studies with reasons for exclusion was maintained. For the studies that were chosen for inclusion at this stage, key data from each eligible study were then extracted and entered into an electronic database.

Searches will be updated while the report is posted for public comment and peer review to capture any new publications. Literature identified during the updated search will go through the same process of dual review as all other studies considered for inclusion in the report. If any pertinent new literature is identified for inclusion in the report, it will be incorporated before the final submission of the report.

PICOTS Framework

Populations of Interest

This review focuses on adults with medical illness and complex care needs. A main criterion in choosing studies for inclusion was the existence of complex care needs. Complex care needs was defined broadly and we included studies with case definitions based on healthcare resource utilization, patient health outcomes, and/or multi-factor assessments that include measures such as socio-economic status or patient self-efficacy. Appendix D provides examples of organizations that have similarly defined complex care needs. The included studies sometimes addressed populations in which psychiatric problems, such as depression, were important comorbid conditions. Studies of CM for dementia were included, because dementia is a clinical problem that often is managed in the primary care setting.

Studies in which the primary clinical problem was a psychiatric disorder (other than dementia) and in which CM was used primarily to manage mental illness or a substance abuse disorder were excluded.

Interventions

The definition of CM used to make decisions about inclusion/exclusion is described in detail in the Introduction section of this report. We define CM as a process in which a person (alone or in conjunction with a team) manages multiple aspects of a patient's care. Key components of CM

include planning and assessment, coordination of services, patient education, and clinical monitoring.

Comparators

In most studies, CM is compared with usual care (i.e., care without a CM component). Usual care can be quite variable across studies and generally consisted of the array of services generally available to the population studied. When a study compared two or more different types of CM, then the comparator was the alternative type of CM. However, in most cases the comparator was the same milieu of clinical services without a distinct CM component. For clinical trials and other studies having a comparison group, we specifically examined the study's reports for information about contamination (provision of CM or other care coordination services to the control group).

Outcomes of Interest

The outcomes of interests are specified in the Key Questions, as follows:

- a. *Patient-centered outcomes*, including mortality, quality of life (QOL), disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care.
- b. *Quality of care*, as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior.
- c. *Resource utilization*, including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits).

These categories were derived from the set of outcomes specified in the descriptions of CM programs described in the literature. These programs address the needs of defined patient populations and have discrete clinical goals. These three categories reflect the categories of goals that usually are addressed in CM.

Comparative effectiveness reviews (CERs) commonly classify outcomes as either benefits or harms. The CM literature has not classified harms of CM. Thus, the outcomes listed above are not classified as either benefits or harms. Thus, if a CM program led to an improvement in mortality, it could be considered a benefit. If it led to worse mortality, it could be considered a harm.

Timing

A level of longitudinal engagement with patients was a criterion for study inclusion. We excluded studies that provided CM for only short durations (30 days or less). This criterion excluded many studies that evaluated short-term post-hospitalization programs (often termed “transitional care” programs). Such programs fall into a large category of inpatient discharge planning activities that are beyond the scope of this review.

Settings

We included only studies in the outpatient setting, including primary care, specialty care, and home care settings. No geographic limitations were applied.

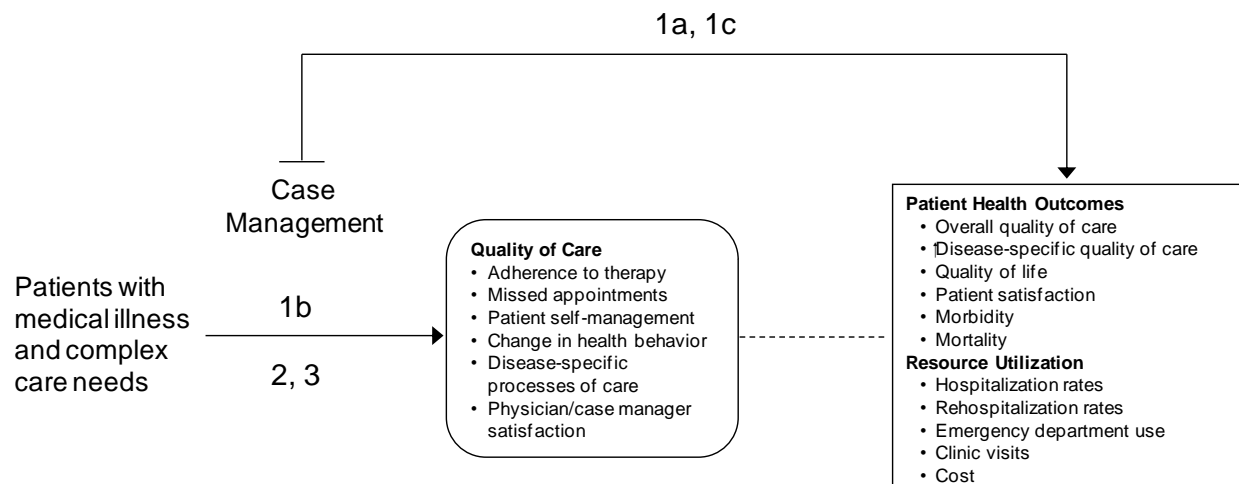
Types of Studies

We included trials and observational studies pertinent to the key questions. We retrieved and evaluated for inclusion and exclusion any randomized trial. We also included studies using quasi-experimental designs and observational studies including cohort, case-control and prepost designs. Previously published systematic reviews were included if their definition of CM was consistent with that used in this project. Inclusion and exclusion criteria are detailed in Appendix C.

Analytic Framework

We developed an analytic framework (Figure 2) that specifies the relationships between the interventions and outcomes. This analytic framework depicts the chain of logic for using evidence to answer the Key Questions.

Figure 2. Analytic framework



Data Extraction and Data Management

After studies were selected for inclusion based on the key questions and PICOTS, the following data were abstracted and used to assess applicability and quality of the study: study design; inclusion and exclusion criteria; population and clinical characteristics (including sex, age, ethnicity, primary disease, comorbidities, complex care needs, and insurance carrier); CM intervention characteristics (including case manager professional identification and prior training); preintervention training for case managers; caseload and the nature of care provided by the intervention (e.g., patient education, coordination of services, medication monitoring, and adjustment); results for each outcome, focusing on the outcomes of interest (patient centered, resource utilization, and process of care outcomes); and if available, we recorded the number of patients randomized relative to the number of patients enrolled, how similar those patients were to the target population, and the funding source. We

recorded intention-to-treat results when available. These data are presented in the evidence tables. All study data were verified for accuracy and completeness by a second team member.

Quality Assessment

We used predefined criteria to assess the quality of individual controlled trials and observational studies. We assessed the quality of randomized trials and cohort and case control studies based on the predefined criteria listed in Appendix E. We adapted criteria from methods proposed by Downs and Black (observational studies) and methods developed by the U.S. Preventive Services Task Force. The criterion used is similar to the approach recommended by AHRQ in the draft *Methods Reference Guide for Effectiveness and Comparative Effectiveness Review*.¹⁵

Individual studies were rated as “good,” “fair,” or “poor” (see Appendix E). Studies rated “good” have the least risk of bias, and results are considered valid. Good-quality studies include clear descriptions of the population, setting, interventions, and comparison groups; a valid method for allocation of patients to treatment; low dropout rates and clear reporting of dropouts; appropriate means for preventing bias; and appropriate measurement of outcomes.

Studies rated “fair” are susceptible to some bias, but it is not sufficient to invalidate the results. These studies do not meet all the criteria for a rating of good quality, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems. The “fair” quality category is broad, and studies with this rating vary in their strengths and weaknesses: the results of some fair-quality studies are *likely* to be valid, while others are only *probably* valid.

Studies rated “poor” have significant flaws that imply biases of various types that may invalidate the results. They have a serious or “fatal” flaw in design, analysis, or reporting; large amounts of missing information; discrepancies in reporting; or serious problems in the delivery of the intervention. The results of these studies are at least as likely to reflect flaws in the study design as the true difference between the compared drugs. We did not exclude studies rated poor quality *a priori*, but poor-quality studies were considered to be less reliable than higher-quality studies when synthesizing the evidence, particularly when discrepancies between studies were present.

Data Synthesis

CM has been studied in a large range of clinical settings and for diverse patient groups. Many CM programs target individuals with particular diseases or clinical needs, and the programs are tailored for those patient needs. Because of the broad range of models of CM, we grouped the studies by the population groups and the clinical problems that were chiefly addressed. For the majority of studies, these groupings were based on particular diagnoses (such as congestive heart failure (CHF), diabetes, or dementia). There also were studies on programs that addressed the needs of older adults that generally fell into one of two groups – older adults with multiple chronic conditions or the frail elderly. We reviewed the findings of the studies for each of these categories and then assessed overall findings (across population groups), as related to the project’s key questions. For most outcomes the amount of heterogeneity among the individual studies precluded formal meta-analyses.

Grading the Body of Evidence for Each Key Question

The strength of evidence for each key question was initially assessed for the outcomes applicable to each patient category. We used the approach described by Owens, et al.¹⁶ to evaluate the body of evidence for each outcome in each patient category. This approach uses the following categories:

- Risk of bias (low, medium, or high)
- Consistency (consistent, inconsistent, or unknown/not applicable)
- Directness (direct or indirect)
- Precision (precise or imprecise).

We also estimated publication bias by examining whether studies with smaller sample sizes tended to have positive or negative assessments of CM effectiveness. Applicability was estimated by examining the characteristics of the patient populations and clinical settings in which the studies were performed.

The strength of evidence was assigned an overall grade of High, Moderate, Low, or Insufficient according to a four-level scale:

- High—High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- Moderate—Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low—Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.
- Insufficient—Evidence either is unavailable or does not permit estimation of effect.

Peer Review and Public Commentary

Nominations for peer reviewers were solicited from several sources, including the CM organizations, researchers, Federal agencies, and members of the TEP. AHRQ made final decisions on all peer reviewers. A list of reviewers submitting comments on this draft will be included in the final report. This draft report also will be publicly posted for 30 days to solicit public comments.

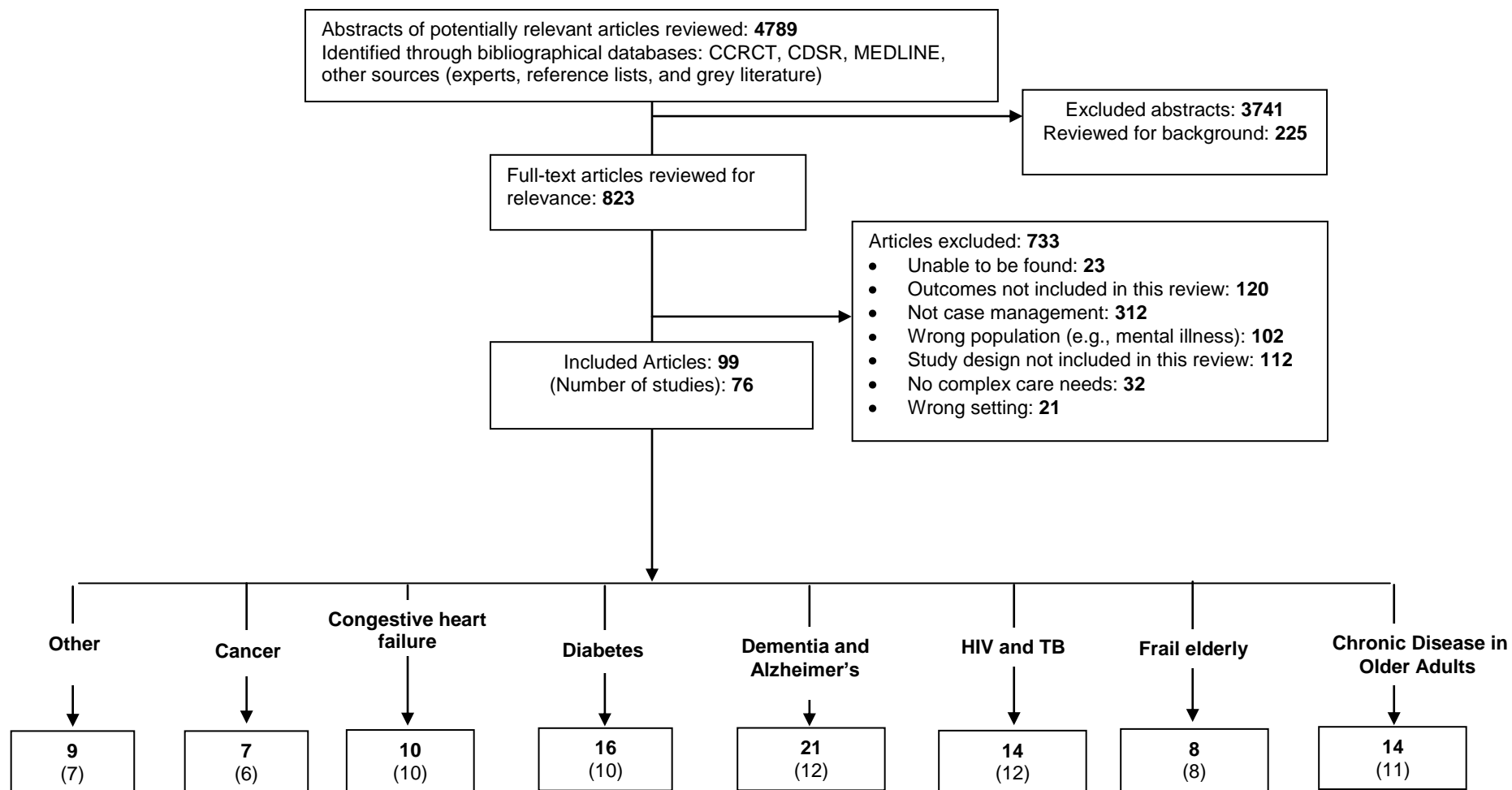
Results

Search Results

A summary of the search results is presented in Figure 3. From the Medline search, we retrieved 2657 unique citations, and the CINAHL search produced 2132 citations that were not duplicated in the Medline search. We also obtained 428 additional citations from a search of the Cochrane databases. A total of 15 additional studies were identified by reviewing reference lists of published studies and systematic reviews.

After a review of the titles and abstracts, 823 were selected as possibly relevant by at least one of the two reviewers. Full articles were retrieved for all of these. After review of the full articles, a total of 83 were selected as relevant by both reviewers. An additional 16 articles were selected as relevant by one of the initial reviewers and then were included after review by a third reviewer who acted as an adjudicator. Thus, a total of 99 published articles were included in this review. Due to multiple publications for some studies, this represented 76 total studies of case management (CM). Appendix F contains a list of excluded studies.

Figure 3. Study flow diagram



Because the published studies often examined specific patient populations, the CM programs focused on the clinical problems of those patient groups. Thus, there is a considerable diversity of programs. Comparisons across programs and populations need to account both for differences in the populations and differences in the content of the CM programs. In general, the published studies provide limited information about how specialized programs are integrated with companion programs that may serve other patient populations. The recent Medicare Coordinated Care Demonstration¹⁷ is one example of a study of programs that served more broadly defined patient populations.

A wide variety of outcomes were included in these studies. After reviewing all of the studies, we categorized the outcomes according to the three parts of Key Question 1. In some cases the patient-centered outcomes were unique to the type of CM programs used for particular patient populations. In some cases outcomes were not used for this report if the methods of measurement were judged inadequate or the outcomes were measured in only one to two studies. The following outcomes were evaluated for strength of evidence:

Key Question 1a: Patient-centered outcomes

Multiple populations

- Mortality
- Quality of life (QOL)
- Functional status
- Patient satisfaction

Dementia

- Ability to remain at home (avoidance of nursing home placement)
- Caregiver stress/burden
- Caregiver depression

Congestive heart failure

- Dyspnea

Cancer

- Symptoms caused by cancer
- Depression

Diabetes

- Glucose control
- Cholesterol control
- Blood pressure control
- Body weight

Key Question 1b: Quality of care

Multiple populations

- Receipt of guideline-recommended clinical services
- Patient self-management behaviors
- Medication adherence
- Missed appointments

Key Question 1c: Resource utilization

Multiple populations

- Hospitalization rates
- Emergency department (ED) visits
- Appointments with primary care and specialty providers
- Receipt of in-home services
- Overall expenditures

Key Question 2: Variation due to patient characteristics

Multiple populations

- Variation among racial/ethnic groups
- Variation among socioeconomic groups
- Variation attributable to social support

Key Question 3: Variation due to intervention characteristics

Multiple populations

- Variation due to intensity of CM
- Variation due to duration of CM
- Variation due to training and supervision of case managers
- Variation due to integration with other clinical programs

In describing the available evidence about the effects of CM programs on these outcomes, we first summarize the evidence for the three Key Questions. We then provide detailed descriptions of the evidence for the patient populations that fell within this report's scope.

Overall Effectiveness of Case Management

The overarching finding of our review is that CM has minimal impact in improving patient-centered outcomes, quality of care, and resource utilization among patients with chronic medical illness. On balance, CM interventions tested in RCTs were more often unsuccessful than successful in improving prespecified outcomes. The most notable example of the limited impact of CM was the Medicare Coordinated Care Demonstration project (MCCD), in which over 18,000 patients, predominantly elderly persons with multiple chronic illnesses, were enrolled in a prospective randomized trial conducted in 15 separate CM programs across the United States¹⁷ Twelve of these 15 programs met our criteria for inclusion in this report. In assessing multiple

outcomes – including health outcomes, quality of care, hospitalizations, and overall expenditures – there were only sporadic and isolated successes. Only three of the programs, one of which was small and could not be sustained, showed potential return on investment.

Although this summative conclusion of minimal impact reflects the balance of findings from our review, it was not a consistent finding across all studies. The studies included in our review comprise a heterogeneous body of evidence with mixed results. In part, this heterogeneity reflects variability in the patient populations for whom CM was implemented. Studies tested CM for the management of specific clinical conditions (e.g., diabetes, dementia) and for patients (usually elderly) with multiple chronic conditions. Some studies enrolled general populations with chronic illness, while others targeted patients with clinical or sociodemographic characteristics that put them at risk for inadequate care, poor outcomes, or high resource utilization (e.g., frail or disabled elders, high utilizers, patients with limited social support). Heterogeneity in the application of CM also extended to the design and implementation of CM interventions. Differences in CM implementation reflected the fact that the goals of CM varied across different clinical conditions, patient populations, and settings. For instance, CM intended to delay nursing home placement for community-dwelling patients with dementia was very different – in content, implementation, and intensity – from CM intended to improve glycemic control among outpatients with diabetes. We therefore started our analysis by synthesizing data for specific patient groups (typically defined by clinical condition), in which the goals of CM interventions were relatively similar. We then sought common themes that cut across groups. For each clinical condition, and for the cross-cutting synthesis, we first focused on the impact of CM on commonly targeted outcomes (KQ1), and then on discerning the specific parameters – patient characteristics (KQ2) and intervention characteristics (KQ3) – under which CM was most effective.

In this section we present the findings of our crosscutting synthesis. The MCCD was a particularly important source of information for this analysis, both because of its size and because of the application of a standardized approach to measurement and outcomes evaluation across multiple CM settings. This standardized evaluation allowed more direct comparison of the 12 CM interventions included in the MCCD that was not typically possible when evaluating the results of other individual studies in our review.

Key Question 1a. In adults with chronic medical illness and complex care needs, is case management effective in improving *patient-centered outcomes*?

Mortality. Patients provided CM did not experience lower mortality in general populations of patients with chronic illness, in the frail elderly, those with AIDS, or in patients with terminal cancer.

Quality of life and functional status. CM interventions produced mixed results in terms of improving patients' quality of life (QOL) and functional status. In general, CM was frequently successful in improving aspects of functioning and QOL that were directly targeted by the interventions. For instance, CM was successful in improving caregiver stress among persons caring for patients with dementia and CHF-related QOL among patients with CHF. The measures used to evaluate QOL and functional status varied across studies, and overall, the

improvements in QOL and functional status achieved by CM were either small or of unclear clinical significance. CM was less successful in improving overall quality of life and functioning, as indicated by global measures not specific to a particular condition.

Ability to remain at home. One measure of the clinical significance of improvements in functioning for elderly patients with chronic conditions is the ability to remain at home and avoid nursing home placement. This outcome was often the primary objective of CM programs for patients with dementia. In most studies, CM was not effective in maintaining patients' ability to live at home. Evidence from one study suggests that a high-intensity CM intervention sustained over a period of several years can produce a substantial delay in nursing home placement for patients with dementia.

Disease-specific health outcomes. The effect of CM on disease-specific outcomes was inconsistent. In some studies, CM had a positive impact on specific symptoms, including pain and fatigue in patients with cancer and depressive symptoms among caregivers of patients with dementia. Notably, however, CM did not have a significant impact on clinical outcomes among patients with diabetes, including glycohemoglobin levels, blood pressure, and lipids.

Patient satisfaction with care. CM interventions were generally associated with improved patient (and caregiver) satisfaction, although satisfaction with CM varied across interventions. Studies measuring patient satisfaction typically reported overall satisfaction with care, rather than satisfaction in specific domains. Some interventions improved patient satisfaction across multiple domains of patients' experience with care, while others did not improve satisfaction in any measured domain. Satisfaction was most substantially improved in the domain of coordination among health care providers.

Key Question 1b. In adults with chronic medical illness and complex care needs, is case management effective in improving *quality of care*?

Disease-specific process measures and receipt of recommended services. CM was effective in increasing the receipt of recommended health care services when it was an explicit objective of the CM intervention. For instance, CM interventions designed to improve cancer therapy for patients with breast and lung cancer were successful in increasing the receipt of radiation treatment, as recommended in clinical guidelines. The effect of CM on guideline-recommended care in general, however, was less consistent. Studies showed only sporadic effects on elements of quality of care, such as receipt of appropriate medications for patients with CHF or diabetes, or receipt of appropriate preventive services for elderly patients. There was no clearly discernible pattern indicating which features of CM interventions were successful in improving patients' receipt of appropriate services.

Patient self-management. CM was effective in improving patients' self-management behaviors, including dietary and medication adherence, for specific conditions such as CHF or tuberculosis, when patient education and self-management support were included within CM interventions.

Missed appointments. Few studies measured the frequency of missed appointments as an outcome of CM interventions.

Key Question 1c. In adults with chronic medical illness and complex care needs, is case management effective in improving *resource utilization*?

Hospitalization rates. Among hospitalized patients at high risk for readmission, CM reduced rehospitalization rates. This effect was most notable among patients with CHF, which is the leading cause of hospitalization in elderly patients. For broader groups of patients with chronic disease, CM did not reduce hospitalization rates in general.

Emergency department use. The effect of CM on emergency department (ED) use was varied. Several studies found reduced ED use in patients receiving CM, but other studies found no effect.

Clinic visits. Few studies measured the frequency of clinic visits as an outcome of CM interventions. Those that did generally showed increases in numbers of outpatient visits.

Overall expenditures. Most studies examining the impact of CM on the overall cost of care showed no significant difference between CM and control groups. For patient populations with high rates of hospitalization (e.g., CHF), CM interventions that substantially reduced hospitalization rates tended to reduce costs as well, since hospitalization was usually the most significant source of health care expenditure.

Key Question 2. Does the effectiveness of case management differ according to *patient characteristics*?

Medical conditions. Individual studies had inconsistent finding on whether CM interventions are more successful for patients with high disease burden. While it is possible that there is a mid-range of disease burden in which CM is most effective, the evidence base does not permit defining how to identify such patients.

Age. Most studies of CM included mainly elderly patients, making it difficult to determine impact of age on CM effectiveness.

Socioeconomic status. Studies did not routinely report the effect of CM according to socioeconomic indicators among enrolled patients. Some studies explicitly targeted low-income populations. There was no apparent pattern to suggest an influence of patients' socioeconomic status on the effectiveness of CM.

Social support. Few studies explicitly evaluated patients' level of social support. In studies that evaluated CM effectiveness in patients with differing levels of social support, CM appeared to be most effective in patients with limited social support, as indicated by being unmarried or living alone. An exception is patients with dementia for which the goal is keeping the patient living at

home. In this case higher social support (a spouse caregiver) was associated with longer success in staying at home.

Formally assessed health risk. Some studies explicitly targeted patients considered to be at high risk of poor outcomes. The methods used to evaluate risk, however, varied substantially across studies. In general, CM was most effective in patients judged to be at high risk. This was particularly true for the impact of CM on hospitalization rates. Patients who were hospitalized at enrollment (and thereby known to be at risk for re-hospitalization), and patients with clinical risk factors for readmission, tended to benefit most from CM.

Key Question 3. Does the effectiveness of case management differ according to *intervention characteristics*?

Setting. CM interventions implemented prior to discharge from a hospital were sometimes successful in preventing readmission. Other characteristics of the setting in which CM were implemented (e.g., integrated health system, home health agency, outpatient clinic) did not clearly influence the effectiveness of CM.

Case manager experience, training, skills. Studies did not consistently provide details about the experience, training, or skills of case managers. In most studies the case managers were nurses, and some had specialized training in caring for patients with the conditions targeted by the CM intervention (e.g., diabetes, cancer). There was some evidence that pre-intervention training of nurses in providing CM for the targeted conditions, the use of protocols or scripts to guide clinical management, and collaboration between a case manager and a physician (or multidisciplinary team) specializing in the targeted clinical condition, resulted in more successful interventions.

Case management intensity, duration, integration with other care providers. Studies across multiple patient groups suggested that more intense CM interventions, as indicated by greater contact time, longer duration, and face-to-face (as opposed to only telephone) visits, produced better outcomes, including functional outcomes and lower hospitalization rates. In addition, CM interventions that were more tightly integrated with patients' usual care providers (typically primary care physicians) tended to produce, on balance, better results. The most successful interventions generally had more contacts between case managers and patients and were more integrated with the hospitals and physicians where patients received care.

Case manager functions. Case managers typically performed multiple functions, including assessment and planning, patient education, care coordination, and clinical monitoring. In general, emphasis on specific functions varied according to patients' conditions and the primary objectives of specific CM interventions. For example, interventions among patients with cancer typically focused on coordination and navigation, while interventions for patients with diabetes and CHF focused more on patient education (for self-management) and clinical monitoring. While some studies carefully measured the amount of effort case managers devoted to different functions, most did not, making it difficult to discern the degree to which emphasis on different case manager functions impacted CM effectiveness.

Effectiveness of Case Management in Defined Patient Populations

Case Management for Older Adults with Multiple Chronic Diseases

Contemporary models of CM use clinical approaches that are applicable to a variety of diseases and conditions. Clinical programs that meet the needs of a broad patient population potentially are more sustainable, and the largest clinical trials of CM have been studies of programs that take a generalist approach. The primary goal of many of these studies has been to determine whether CM can reduce health care expenditures, by preventing acute hospitalizations and reducing use of other expensive services. At the same time, CM programs for the elderly frequently have been dominated by approaches that attempt to define *subpopulations* at particular risk. The basic premise is that a healthy, highly functional older adult is less likely to need CM than one of the same age who is somewhat more ill. Selection of older adults for inclusion in CM, therefore, has taken a wide variety of approaches. These include purely administrative assessments, such as previous utilization, especially hospitalization, certain chronic illnesses, or prior costs of care. Evaluations of such CM programs are included in this section. Subsequent sections of this report will review the evidence about programs that select participants on the basis of either, to more targeted assessments of patient-reported functional and health status (the frail elderly) or on the basis of specific clinical diagnoses such as dementia or congestive heart failure.

Description of Studies

We identified five randomized controlled trials of CM programs that delivered services to broad populations of older adults (see Appendix H). All five were rated good quality (see Appendix G). Four were conducted in the United States,¹⁷⁻²⁰ and the remaining trial was conducted in Australia.²¹ These trials were published between 2003 and 2011. In addition to the five randomized controlled trials, we identified two studies of CM for community-dwelling Medicare populations that used non-experimental designs.^{22, 23} Both of these studies examined groups of patients who received case management services in existing programs and used matching techniques to construct comparison groups. We also identified five other observational studies that used either historical controls, a nonequivalent comparison group, or did not have a comparison group²⁴⁻²⁸ (see Appendix H).

Two other closely related clinical approaches have been developed for older adults with chronic diseases. These were not included in this review, based on our definition of CM. First, team-based geriatric practices, including the intensively studied Program for All-Inclusive Care of the Elderly, were excluded because they tended to have provider-led interventions, and the role of the case manager was less clear in most of them. Rather, these approaches tended to involve team-based discussion and coordination that was either the source of primary care or essentially replaced primary care. Similarly, the Geriatric Resources for Assessment and Care of Elders (GRACE) project²⁹ also was excluded. This model used home based care by a team consisting of a nurse practitioner and social worker to provide guidance and assistance to older adults. Second, many care transition interventions (managing the transition from hospital to home, for instance) were excluded because of a short duration of the intervention (less than 6 months).

The largest randomized trial of CM was conducted between 2002 and 2005 in multiple sites in the United States.¹⁷ Known as the Medicare Coordinated Care Demonstration (MCCD), the study was funded by the Centers for Medicare & Medicaid Services (CMS). The 15 clinical sites had submitted proposals to CMS to participate in the project. The evaluation was managed by a separate organization that collected all outcome data. Participants were enrolled and randomized through 2005. Because each clinical program was managed separately, this study is in fact a set of single-site clinical trials, each using identical methodology. The study reports¹⁷ listed outcome data separately for each site. Of the 15 sites, one was a hospice program, one was conducted in a long-term care facility, and one did not provide care coordination. Because these did not meet our definitions for study setting or intervention characteristics, we dropped these three sites from our analyses, leaving 12 sites used for this report. The total sample size for these 12 sites was 16,301. There was a significant variation in size across these 12 sites, ranging from 211 to 2657 participants per site. For all five of the clinical trials in this category, the total number of participants is 29,442.

The *populations* in the four U.S. trials were Medicare beneficiaries living independently who were judged to be at high risk of medical complications and the attendant utilization of health care services. Eligibility criteria for all but one of the programs included in the MCCD trial¹⁷ included one or more targeted chronic conditions; seven of the 12 programs also required a recent hospitalization – either within a year prior to enrollment (6 programs) or within the prior 60 days (1 program). The average monthly Medicare expenditures at baseline for the study sample overall was nearly 3 times that of beneficiaries nationwide; baseline expenditures for study participants in six programs averaged more than \$2000 per month, but less than \$600 per month in three programs. In the study reported by Boulton et al,²⁰ participants were identified as being at high risk of heavy health services use during the upcoming year by using a claims-based predictive model. Study participants (n=904) had four chronic diseases on average, over 40 percent rated their health as fair/poor, and 25-30 percent had diminished functional status by ADL or IADL measures. The study reported by Newcomer et al,¹⁹ had enrollment criteria of *either* being age 80 years or older *or* being 65 or older with at least one qualifying chronic condition; over 70 percent of the sample population (n=3079) was 80 years or older, which is a notable difference compared with the percentage of this age group in the other study samples. The study reported by Martin et al,¹⁸ also had a notable difference in the study sample; enrollment was open to all members of an HMO who resided within the study catchment area and were at least 65 years of age (n= 8504). During the study period, a total of 1640 participants in the intervention group (38.5 percent) were evaluated for CM based on an electronic algorithm or a low score on a general health measurement. The study conducted in Australia (n=654)²¹ enrolled participants being discharged from an acute hospitalization who had mobility or self-care management problems. The mean age of participants was 77 years, and they had an average of two comorbidities.

CM *interventions* in these studies focused on patient self-management education, health status monitoring, and coordination of health care (see Table 2). Case managers in all of the studies were nurses (or hospital staff with nursing or allied health backgrounds).²¹ Across studies, the vast majority of contacts with patients were via the telephone. In-person contacts generally were reserved for initial assessments, although in four programs included in the MCCD trial,¹⁷ participants were contacted in person nearly once a month. In the study with post-acute care CM, in-person visits were noted but the frequency not reported.²¹ The length of CM intervention was 6 months in one trial,²¹ 12 months in one,¹⁹ and 20 months in one.²⁰ In the

MCCD trial,¹⁷ programs varied widely in participant's average length of exposure to a CM intervention, with a range of 18 to 38 months. One study¹⁸ did not report exposure time for the participants who received CM during the study period. In one study, CM was managed via teams having caseloads of 800-1000 study participants on each of four teams. A small fraction of the cases (50-70 participants per team) received more intense CM.¹⁸

Table 2. Characteristics of case management interventions for older adults with multiple chronic diseases

Author Year Quality	Duration (months)	Mode(s) of Contact	Main CM Functions	Contacts (average)	Caseload	Role of Usual Care Provider	Supervision by Physician	Profession	Pre- intervention Training	Use of Protocols or Scripts
Boult 2011 Good	20	In-person and telephone.	<ul style="list-style-type: none"> • Assessment • Planning • Clinical monitoring • Transitional care • Coordination • Education • PS Support 	NR	50-60	Integrated	Yes	RN	Yes	Yes
Lim 2003 Good	6	In-person and telephone	<ul style="list-style-type: none"> • Assessment • Planning • Coordination 	NR	NR	Not integrated	No	Nurse or allied health professional.	NR	NR
Martin 2004 Good	18	In-clinic and telephone	<ul style="list-style-type: none"> • Assessment • Planning • Education • Coordination 	NR	50-70	Integrated	Yes	Nurse	NR	Yes
Newcomer 2004 Good	12	Telephone	<ul style="list-style-type: none"> • Assessment • Planning • Coordination 	7.7 hours of contact per year for each patient	1:60 actively managed at any one time (caseload 250)	Integrated	Yes	Nurse	NR	NR
Peikes 2009 Good	3 years	Telephone; In-person contacts (generally reserved for initial assessments, although nearly once a month for four programs).	<ul style="list-style-type: none"> • Education • Clinical monitoring 	Overall number of contacts (range per month): (1.2-8.2) In-person contacts (range per month): (0.09-0.97)	Generally between 50 and 100 (range 1:30 to 1:200)	Generally integrated – varying degrees	NR	RN (11 programs) LPN (1 program)	Yes	Yes

Abbreviations: CM, case manager; LPN, licensed practical nurse; NR, not reported; PS, psycho-social; RN, registered nurse.

The *comparator* in these trials was “usual care,” meaning the standard services provided in each study setting but without the CM intervention.

All of these trials examined both utilization and health status *outcomes* (see Table 3). Patient centered outcomes included mortality, measures of mental and physical health, quality of life (QOL), and patient satisfaction. Quality of care outcomes also were examined in the MCCD trial¹⁷ and included measures of self-management support, service arrangement, and general and disease-specific preventative care. Resource utilization measures included hospitalizations, skilled nursing facility admissions, ED utilization, outpatient visits, home care, and overall costs.

The *timing* of the CM interventions in two of the studies^{17, 20} was similar, in that participants were identified as already being high utilizers of health care services. CM was initiated to improve patient health and reduce the need for ED, hospitalization, and acute care services. In one study, CM was initiated upon hospital discharge after an acute event;²¹ in one study,¹⁹ CM was initiated proactively among a population with increased risk of high service utilization due to advanced age or chronic conditions; and in one study,¹⁸ the CM intervention was offered to a subset of disease management program participants at a point when their health care needs were deemed to have become complex.

The *settings* of the CM programs varied; the MCCD trial¹⁷ included three hospital-based programs, five commercial disease management or care coordination programs, two programs operated in academic medical center, a program in an integrated health care system, and one in a retirement community. The majority of these programs serviced large metropolitan areas, but four serviced rural areas. In the other three studies conducted in the United States,¹⁸⁻²⁰ the CM programs were health plan based or health system based and the study conducted in Australia was hospital-based.²¹

Key Points

Evidence about Patient-Centered Outcomes

- CM programs that serve patients with multiple chronic diseases do not reduce overall mortality (strength of evidence: high).
- CM programs that serve patients with multiple chronic diseases do not result in clinically important improvements in functional status (strength of evidence: high).

Evidence about Quality of Care

- CM programs that serve patients with multiple chronic diseases increase patients’ perceptions that their care is better coordinated (strength of evidence: moderate).

Evidence about Healthcare Utilization

- CM programs that serve patients with multiple chronic diseases do not reduce overall rates of hospitalization (strength of evidence: moderate).
- CM programs that serve patients with multiple chronic diseases do not reduce Medicare expenditures (strength of evidence: high).

Evidence about Patient Characteristics

- CM is more effective for reducing hospitalization rates among patients with greater disease burden (strength of evidence: low).

Evidence about Intervention Characteristics

- CM is more effective for preventing hospitalizations when case managers have greater personal contact with patients and physicians (strength of evidence: moderate).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Four clinical trials and two quasi-experimental studies examined mortality among patients who received CM. In the MCCD trial,¹⁷ 3-year mortality rates ranged from 10 percent to 40 percent for the 11 programs for which mortality was reported. Mortality rates were slightly lower in six of these programs and higher in the other five. There was no significant trend toward reduced mortality with CM.

Mortality

Overall mortality rates in three other trials were low. In Martin's trial,¹⁸ 19-month mortality was 4 percent in the CM group and 5 percent in the control group. Newcomer¹⁹ reported 12-month mortality of 3 percent in both the CM and control groups. In the Australian trial, 6-month mortality rates were 6 percent in both the CM and control groups.

One quasi-experimental study reported a mortality benefit with CM.²³ In this study of U.S. Medicare beneficiaries the CM group included patients who were referred to and completed intake into a CM program linked to primary care clinics. The comparison group included patients followed in similar clinics that did not have CM programs. Patients in the comparison group were selected by matching for age and diagnosis. Two-year mortality rates were 13 percent in the CM group and 17 percent in the control group. This difference was marginally significant ($p = 0.07$).

Another U.S. quasi-experimental study examined mortality over 5 years of followup and found no effect of CM on this outcome. Two family medicine clinics were compared, with only one offering a CM program. Study participants in both clinics were individuals who had three or more clinic visits in the prior year. Average age of the participants was 76 years, and the CM was provided by a nurse practitioner based in the experimental clinic. Five-year mortality was 27 percent in both groups. A European fair-quality observational study found the same mortality rate (16 percent at one year) between a CM group and a comparison group of similar age.²⁸

Functional Status

Evidence about functional outcomes was reported in three clinical trials. The MCCD trial¹⁷ conducted surveys of random samples of participants 10 months after entry into the study. One site did not participate in the survey due to dropping out of the study; another site did not participate because of program focus (enrolled only patients receiving active cancer treatment). For the remaining 10 sites, response rates were reported to be about 95 percent. Sample sizes were at least 350 participants in each of the CM and control groups for each site. The MCCD collected self-reports for activities of daily living (ADLs) and instrumental activities of daily living (IADLs). In none of the programs was there consistent improvement in ADLs or IADLs with CM. Martin¹⁸ also used a survey measure to assess patient functioning at 18 months. The only significant change was a slightly lower rate of deterioration of social functioning in the CM group. Newcomer¹⁹ also found no difference between CM and control groups in measures of physical and mental functioning at 12 months.

Psychological Measures

The MCCD trial¹⁷ also examined psychological measures in the 10-month participant survey. Three of the 10 programs found significantly better scores on a measure of stress in the CM groups. However, CM was not associated with better scores on a depression screen in any of the programs. Another trial examined measures of caregiver depression and burden but found no difference in these measures between the CM and control groups. This finding did not change when evaluating subgroups of caregivers who had higher and lower levels of time commitments to caregiving.³⁰

Patient Satisfaction

Two trials assessed participant satisfaction. The MCCD survey included four items on satisfaction with explanations received from providers. There were no consistent trends in these measures for any of the ten programs when comparing the CM and control groups. Another trial evaluated a measure of overall satisfaction with the health care provided by the patient's regular care team. This rating was significantly higher in the CM group at 18 months.³¹ In this same study, caregiver perceptions of overall quality of care also were higher in the CM group.³²

Quality of Care Outcomes

The MCCD survey included two types of quality measures: perception of care coordination and self-care behaviors. In eight of the ten programs in the MCCD trial, participants in the CM group gave higher ratings of the impression that clinicians kept in touch with each other, and this difference was statistically significant in six.¹⁷ The MCCD survey also included several measures of health behavior associated with chronic illness care. No more than one program showed an effect of CM on each of four measures of diet and exercise. None of the programs showed differences between the CM and control groups for self-reported medication adherence. In addition, none of the programs showed an effect of CM on a question about planning for physician visits. In another trial, both patients and caregivers were asked to rate care coordination. Both patients and caregivers in the CM group gave significantly higher ratings.^{30, 31} None of the other trials included measures of care coordination or self-care.

Using Medicare claims data the MCCD trial also measured receipt of preventive services. There were no consistent effects of CM on vaccination rates or rates of colon cancer screening.¹⁷ Two of 11 programs had higher mammography rates in the CM group.¹⁷ For patients with diabetes, effects of CM on quality measures were mixed. One of 11 programs had higher rates of eye examinations and microalbumin measurements with CM. Two other programs had higher rates of glycosylated hemoglobin testing with CM. In three out of 11 programs, CM was associated with higher rates of lipid testing among patients with diabetes and/or coronary disease.¹⁷

An observational study having a prepost design examined changes in physiological measures with three months of CM.²⁶ Blood pressure, glucose and cholesterol levels decreased moderately, compared with the pre-CM values. However, there was no non-CM comparison group in this study.

Resource Utilization Outcomes

All five of the randomized trials and both quasi-experimental studies included utilization outcomes. The most common utilization measure was hospitalization rates. In the MCCD study, one of the 12 programs found a significantly lower hospitalization rate in the CM group.¹⁷ This program had a per capita yearly hospitalization rate of 0.98 in the control group and 0.82 in the

CM group. A second program that had a high hospitalization rate in the control group (per capita rate of 2.1) had a marginally significant ($p=0.07$) reduction in the rate to 1.6 with CM.

There were similar findings in the other clinical trials. Newcomer¹⁹ found no difference between the CM and control groups in the following measures: overall hospital admissions, readmissions, or nursing home admissions. Boulton²⁰ also found no significant difference between CM and control groups in the rates of hospital admissions, 30-day readmissions, and nursing home admissions. Boulton did find an interaction between insurance coverage and CM effects on nursing home admissions. There was a greater reduction of nursing home admissions with CM for members of a staff-model health maintenance organization than for patients covered by fee for service plans.²⁰ Hospital admissions and total inpatient days also were not different between CM and control groups in the trial reported by Martin.¹⁸ Martin's study found that nursing home admission rates were low in both groups (less than 4 percent per year), but total nursing home days was modestly lower in the CM group.¹⁸ In the Australian trial, hospital admission rates were similar over 6 months in the CM and control groups, but total inpatient days were higher in the control group.²¹

Two quasi-experimental studies and three observational studies had differing findings on hospitalizations. In the first quasi-experimental study, 2-year hospitalization rates were not significantly reduced (32 percent in CM group; 35 percent in control group).²³ The second quasi-experimental study²² also found no difference between CM and control groups in hospitalization rates or total inpatient days. A fair-quality European observational study found 1-year rates of nursing home placement to be 7 percent in the CM group and 13 percent in the comparison group.²⁸ An Australian observational study compared acute hospitalization rates for patients currently receiving CM to rates during the 12 preceding months. The rates were 28 percent lower, while the rates did not change in a comparison group.²⁴ Another poor-quality observational study reported a significant reduction in hospital admissions with CM over a six-month period.²⁵

Two trials and two observational studies examined ED visits. Both the Boulton and Newcomer trials found no difference in ED visits between the CM and control groups.^{19, 20} However, a quasi-experimental study found significantly lower rates of visits to both EDs and urgent care clinics in the CM group.²² An Australian observational study also found lower ED visit rates in a CM group, compared with the 12-month period prior to enrolling in CM.²⁴

In this population, there are not consistent findings on the effect of CM on the utilization of a variety of outpatient services. A trial²⁰ and a quasi-experimental study²² both found no effects of CM on rates of primary care or specialty clinic visits in the United States. The U.S. trial also found that the CM group had significantly lower use of home health services.²⁰ However, the Australian trial found higher use of home nursing and caregiver services but lower use of Meals on Wheels with CM.²¹ An observational study of European programs found no difference in utilization of home nursing, caregiver services, physical therapy, and occupational therapy between a CM group and a comparison group.²⁸

In this population, CM has minimal effects on the overall costs of care. In the MCCD trial, none of the 12 programs had significantly lower overall Medicare expenditures in the CM group.¹⁷ Total costs also were not significantly different between CM and control groups in another U.S. trial.¹⁸ Another U.S. trial measured only the costs of inpatient hospitalizations. It found no difference between the CM and control groups.¹⁹

Table 3. Characteristics and outcomes of studies of case management for older adults with multiple chronic diseases

Author Year Quality	Patient Population	Disease Severity	Setting	Sample Size	Health Outcomes	Patient and CG Experience	Quality of Care	Resource Utilization, Cost
Boult 2011 Good	Older adults (age 65 years or older) with multiple morbidity	High risk of heavy health services use; Four chronic diseases on average	Community- based primary care practices within three health care systems	904	NR	↑Quality of care ratings = Caregiver depression, stress, productivity	NR	= Hospitalizations, SNF admissions, ED visits, OP visits (<i>overall and in highest risk subgroup</i>) Fewer SNF admissions and days (<i>analysis of insurance subgroups, ↑ for Kaiser-insured</i>) ↑ Fewer home health care episodes
Lim 2003 Good	Age ≥ 65 years discharged from an acute hospitalization	Mobility or self- management problems; Required community services on discharge	Hospital-based programs, Victoria, Australia	654	= Mortality ↑Independent living, Overall QOL	= Caregiver stress	NR	= Hospital readmissions, ED visits ↑ Fewer hospital days ↑Lower hospital and community service costs
Martin 2004 Good	Medicare beneficiaries (Medicare Choice Plus) >65 years old	NR	HMO	8504	= Mortality = General health, mental health, physical function ↑ Social function	↑ Satisfaction with health care plan	NR	= Hospital admissions and days, SNF admissions ↑SNF days = Cost
Newcomer 2004 Good	High-risk elderly (age ≥ 80 years or age ≥ 65 with at least one chronic disease condition)	70% of participants ≥ 80 years old	Health-plan based	3079	= Mental and physical health	NR	NR	= Hospital days, ED visits, Nursing home admissions

Author Year Quality	Patient Population	Disease Severity	Setting	Sample Size	Health Outcomes	Patient and CG Experience	Quality of Care	Resource Utilization, Cost
Peikes 2009 Good	Medicare beneficiaries covered by FFS/traditional Medicare with one or more chronic conditions	High utilizers of health care services; Recent hospitalization (7 of 12 programs)	Hospital-based programs (3), commercial disease management or care coordination programs (5), academic medical center programs (2), integrated health care system program (1), retirement community (1). Four programs serviced rural areas	16,301 (program ranges 211 – 2657)	↑=↓ (mixed results): Functional status	↑=↓ (mixed results): Patient satisfaction ratings	↑ Receipt of health education ↑= (mixed results): General and disease-specific preventive services = Self-management understanding and adherence	Annual hospitalizations: = (10 programs) ↑ (1 program) ↓ (1 program) = Overall Medicare expenditures (Subgroup Analysis - 1 program; hospitalizations and expenditures: ↑ for highest risk subgroup)

Abbreviations: CG, caregiver; ED, emergency department; FFS, fee-for-service; HMO, health maintenance organization; NR, not reported; OP, outpatient; SNF, skilled nursing facility.

↑ Better with case management; = No difference; ↓ Worse with case management.

Effectiveness of Case Management by Patient Characteristics

Although the studies of CM in this population group included large numbers of participants, there were few analyses of patient sub-groups. One of the programs included in the MCCD study conducted a risk stratification of its participants at the time of enrollment. For the 30 percent of participants having the highest severity, hospitalization rates were 29 percent lower with CM, and total expenditures were 20 percent lower. This higher risk group was defined as patients having average Medicare monthly expenditures of between \$900 and \$1200 per month.¹⁷

One quasi-experimental study compared mortality and hospitalization rates among people with diabetes to the entire population of participants.²³ In the sub-group of patients with diabetes, 2-year mortality rates were similar to those in the entire patient sample. However, those who received CM had significantly lower mortality (18 percent vs. 13 percent at 2 years).

The hospitalization rate also was significantly lower with CM (30 percent in CM group; 39 percent in control group).²³ No other studies have examined sub-groups of people with diabetes for these outcomes.

Effectiveness of Case Management by Intervention Characteristics

In the MCCD study, the two CM programs that had the strongest effect on reducing hospitalization rates were compared with the remaining programs by a variety of programmatic characteristics. Several differences were found. First, the two successful programs averaged one in-person contact between the patient and case manager per month, compared with a median of 0.3 such contacts in the other programs. Second, participants in these two successful programs were more likely to report that they had received instructions on how to take their medications. Two other characteristics of the successful programs were that they were closely linked to providers. The case managers frequently traveled to primary care sites for direct communication with physicians and also had close contacts with hospitals to provide close followup after acute hospitalizations. Another feature of the successful CM programs was the continuity of the case manager, defined as a single case manager assigned to each physician's patients.¹⁷

Indirect comparisons can be made between the MCCD study and other trials by intervention characteristics. The large trial reported by Martin¹⁸ featured high caseloads by the case managers and consequently little face-to-face patient contact. This trial showed few benefits of CM. The Newcomer trial¹⁹ also had relatively high caseloads (about 250 per case manager), and this study found minimal benefits of CM. These findings suggest that CM effectiveness may be related to face-to-face time with patients.

Case Management for the Frail Elderly

As people with multiple chronic illnesses age, the cumulative result is a declining ability to live independently. CM programs potentially can help the frail elderly to avoid or reduce functional loss, improve quality of life, and maintain independence. For people who are frail, these programs also have the potential to forestall hospitalizations, ED visits, and skilled nursing facility use. The reduction of utilization of these services potentially can be accomplished through coordinating care for complex illnesses, preventing adverse events (such as urinary tract infections, pressure ulcers, falls, and the like), and preventing disease exacerbations. The approach to CM is often broad and holistic so as to meet the needs of individual patients, rather than an emphasis on single disease indicators. Case managers also need to coordinate care for multiple chronic diseases.

Description of Studies

We found five randomized controlled trials of CM programs for the frail elderly (see Appendix I). Two were rated good quality,^{33, 34} two were rated fair,^{35, 36} and one was rated poor³⁷ (see Appendix G). The trials were conducted in the United States,^{34, 36} Canada,³⁷ Italy,³³ and Hong Kong.³⁸ The studies were published between 1998 and 2008. Sample sizes ranged from 92 to 792 participants (total N = 1,803). We also identified three observational studies of CM for the frail elderly. One was rated as having good methodological quality,³⁹ one was rated fair,⁴⁰ and one was rated poor.⁴¹ All were conducted outside the United States and defined cases on the basis of older age and presence of functional deficits.

The *populations* in the clinical trials were all elderly with some marker of frailty. All used an assessment of functional status in screening patients for eligibility, primarily through assessment of activities of daily living (ADLs) or instrumental ADLs (iADLs). Mean patient age ranged from 74 to 82 years, with the mean in three studies being 80 or older.^{33, 37 36} Two trials included a recent hospital admission or ED visit among the eligibility criteria.^{37, 38}

CM *interventions* in these studies focused on health care and community resource coordination (see Table 4). The clinical functions most often assessed were propensity to fall or functional status. Case managers were most commonly nurses, although some studies utilized other type of health care worker with geriatric expertise (e.g., physician assistant, social worker, allied health worker). Average caseloads (reported in only four studies) numbered 10, 20, 45, and 70. Interventions almost uniformly involved home visits in addition to telephone followup; the frequency of contacts varied between studies. The case manager in one study initiated contact during a clinic visit and subsequent contact was via telephone only.³⁴ Most study interventions were for 6 or 12 months; there was a 10-month study³⁷ and a 24-month study.³⁶ In general, reporting of case manager activity and location was poor; few studies identified how much the case manager interacted with the patient. *Comparators* for CM were dependent on setting. In each study the comparator was usual care but without the CM component. The hospital-based study³⁸ used usual hospital discharge services as comparators, the health care plan-based study³⁶ used usual plan care, one study³⁴ used usual primary clinic care, and two^{33, 37} used the package of home care and community services available to all study participants.

Table 4. Characteristics of case management interventions for the frail elderly

Author Year Quality	Duration (months)	Mode(s) of Contact	Main CM Functions	Contacts (average)	Caseload	Role of Usual Care Provider	Supervision by Physician	Profession	Pre- intervention Training	Use of Protocols or Scripts
Bernabei 1998 Good	12 months	Home visits	<ul style="list-style-type: none"> • Assessment • Monitoring • Coordination 	Every 2 months	20	Integrated	Yes	Trained in geriatric assessment and CM	Yes	NR
Gagnon, et al. 1999 Poor	10 months	Home visits, phone	<ul style="list-style-type: none"> • Assessment • Monitoring • Coordination 	3.6 home visits/ month 2.8 calls/ month	45	Integrated	Yes	Nurses with geriatric experience	Yes	NR
Leung, et al. 2004 Fair	6 months	Phone, home visits if needed	<ul style="list-style-type: none"> • Assessment • Monitoring • Coordination 	NR	10	Integrated	Unclear	Trained in nursing elderly patients	NR	NR
Rubenstein 2007 Good	12 months; followup at 2 and 3 years	Phone	<ul style="list-style-type: none"> • Assessment • Monitoring • Coordination 	Every 3 months	NR	Integrated	Yes	Physician assistant with geriatric expertise	NR	NR
Long 1999; Marshall 2000 Fair	24 months	Home visits, phone	<ul style="list-style-type: none"> • Assessment • Monitoring • Coordination 	NR	70	Integrated	Yes	Nurse and social worker with prior geriatric CM experience	NR	Yes

Abbreviations: CM, case management; NR, not reported.

Targeted *outcomes* in the trials included patient centered outcomes and resource utilization (Table 5). Patient centered outcomes included mortality, measures of mental and physical health and functional status, satisfaction with health care, quality of life (QOL), and measures of caregiver burden. Resource utilization measures included ED utilization, hospitalizations, nursing home admissions, outpatient visits, community service use, and overall costs. One study³⁴ measured a quality outcome: the recognition and evaluation of common geriatric clinical problems.

The *timing* of the CM interventions varied and depended on how the study populations were identified. In essence, the interventions were initiated either in the course of the slow process of becoming frail or following a high risk clinical event. In three studies, CM interventions were initiated for participants with a recent history of hospitalization or ED use;^{37, 38, 42} one was initiated for participants enrolled or enrolling in a home-care assistance program;³³ and one was initiated in a population already followed in a primary care practice.³⁴

Settings for the trials varied; one was health plan-based,^{36, 37} one was hospital-based³⁵ one was conducted within the Veterans Affairs Medical Center (VAMC) health care system³⁴ and two were community-based within national health care systems.^{33 37}

Key Points

- CM does not affect mortality in frail elders (strength of evidence: low).
- Evidence is insufficient to assess the effect CM on functional status in the frail elderly.
- CM does not decrease acute hospitalizations in the frail elderly (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Mortality

Both of the good-quality trials measured mortality, and both found no reduction in the intervention group at one year³³ or three years of followup.³⁴ A fair-quality trial³⁵ reported 12-month mortality of 4 percent in the intervention group and 9 percent in the control group, but this study had a total sample size of only 92, so there is low confidence in this difference. The other two trials did not report mortality. A fair-quality observational study⁴⁰ also reported no difference in one-year mortality between the CM and comparison groups.

Functional Outcomes

There is marked heterogeneity in the studies of the frail elderly on the effects of CM on functional status. The study reported by Rubenstein and colleagues³⁴ was rated as having good methodological quality, had the largest sample size, and the longest followup (3 years). This study found that measures of functional status did not change significantly over time in either the CM or the control group. However, the other good-quality trial³³ found significantly better improvement in ADLs in the CM group. A fair-quality trial³⁶ found no change in ADL or IADL scores in the CM group over two years but worsening of these scores in the control group. The two other trials^{35, 37} also found no difference between CM and control groups in ADL or IADL scores over 10-12 months. A poor-quality observational study⁴¹ found improvement in functional status with CM, but a fair-quality observational study⁴⁰ did not find improvement with CM in their frail elderly group.

Quality of Care Outcomes

One good-quality trial³⁴ had measures of the process of care as a primary outcome. This evaluation focused on five geriatric conditions and was assessed by medical record review. Documentation of all five problems was substantially higher for the CM patients. Clinical evaluation of the problems also was higher in the CM group. None of the other studies evaluated such outcomes.

Resource Utilization Outcomes

A primary rationale for CM for the frail elderly is to avoid unnecessary hospitalizations or ED visits. All eight of the studies examined one or more utilization measures. In the good-quality trial by Rubenstein,³⁴ about one-third of participants in both groups were hospitalized in each of three years of followup, with no difference in rates between the CM and control groups. In the other trial conducted in the United States³⁶ hospitalizations rates averaged 37 percent per year, without a significant difference between the CM and control groups. Significant difference was not found in hospitalization rates between CM and control groups in either the trial conducted in Canada^{37, 40} or in a Canadian observational study.⁴¹ However, trials conducted in Italy³³ and Hong Kong³⁸ found reductions in hospitalization rates with CM. Three trials looked at changes in ED visits. Marshall³⁶ found no effect of CM on ED visits in the United States, while Gagnon found that CM was associated with higher rates of ED visits in Canada. In the Italian study,³³ the CM group had significantly fewer ED visits. One trial³³ also examined nursing home admissions and found no difference between the CM and control groups over 12 months.

CM has variable effects on use of outpatient services. The good-quality U.S. trial³⁴ found that outpatient referrals to a variety of specialty services were significantly higher in the CM group than in the control group. However, the other U.S. trial³⁶ found no significant difference in the numbers of outpatient visits between the CM and control groups. The trial conducted in Hong Kong^{35, 36} found only small changes in outpatient visits with CM.

Two of the trials evaluated costs of care. The fair-quality U.S. trial estimated total costs of care using approximations.³⁶ The estimated costs were higher in the CM group than in the control group in both years of the study. The Italian trial³³ also used an approximation method to estimate costs and found total costs to be significantly lower in the CM group, primarily due to the lower hospitalization rate.

Table 5. Characteristics and outcomes of studies of case management for the frail elderly

Author Year Quality	Patient Population	Sample Size	Health Outcomes	Quality of Care	Resource Utilization, Cost
Bernabei et al. 1998 Good	Mean Age = 80 Recipients of home health services or home assistance programs	199	= Mortality ↑ Functional status	↑ Evaluation of geriatric conditions	= Hospitalizations ↑ Fewer ED visits = Nursing home admissions
Gagnon et al. 1999 Poor	Frail elderly post- discharge from the ED at risk for hospitalization	427	= Functional status	NR	= Hospitalizations ↓ More ED visits
Leung et al. 2004 Fair	Frail elderly with two or more chronic illnesses and recent repeat hospitalizations	92	↓ Mortality = Functional status	NR	↑ Fewer hospitalizations
Rubenstein et al. 2007 Good	Age ≥ 65 years Elderly population with problems such as falls, urinary incontinence, depression, memory loss, and functional impairment	792	= Mortality = Functional status	NR	↑ Fewer hospitalizations
Long and Marshall 1999; Marshall et al. 2000 Fair	Age ≥ 75 years with poor functional status, high utilizations of ED and/or hospital	317	↑ Functional status	NR	= Hospitalizations and ED visits

Abbreviations: ED, emergency department; NR, not reported.

↑ Better with case management; = No difference; ↓ Worse with case management

Effectiveness of Case Management by Patient Characteristics

The modest sample size of the trials of CM for the frail elderly generally precludes subgroup analysis within this patient category. No studies examined age as a variable, and there generally were not good measures of comorbidity burden. There is no particular patient subgroup that appears to achieve greater success with CM.

Effectiveness of Case Management by Intervention Characteristics

The studies of frail elders generally included little information about the intensity of CM delivered, although all used relatively low (less than 100 patients) caseloads for the case managers. The greatest variation in outcomes was in measures of functional status, but none of the studies identified unique program characteristics that were linked to better functional outcomes.

Case Management for Patients with Dementia

Dementia is a disabling chronic disease for which the prevalence steadily increases with advancing age. It is estimated that about 14 percent of people in the United States who are older than 70 currently have dementia.⁴³ People with dementia have decreasing functional abilities over time, requiring the assistance of caregivers for their daily needs. Providing such assistance in institutional settings (such as nursing homes) is expensive and often is associated with

isolation and medical complications. Avoiding or delaying placement in nursing homes has been widely regarded as a desirable clinical goal. There have been many major initiatives to examine possibly beneficial interventions. CM is one approach that has been studied.

Description of Studies

We identified 12 randomized controlled trials of CM programs for patients with dementia (see Appendix J); seven were rated good quality,⁴⁴⁻⁵⁰ one rated fair quality,⁵¹ and four rated poor quality⁵²⁻⁵⁵ (see Appendix G). The trials were conducted in the United States,^{44, 48-50, 53-55} the United Kingdom,⁵⁰ Hong Kong,⁵¹ Canada,⁵² Finland,^{45, 46} the Netherlands,⁴⁷ and Australia.⁵⁰ They were published between 1990 and 2011. Sample sizes ranged from 78 to 8,138 participants (total N = 10,058). However, the majority of these studies were relatively small with nine of the 12 trials having fewer than 100 participants in their CM intervention arms.^{44-47, 50-54}

The *populations* in all 12 studies were patients with dementia still living at home. The majority of patients lived with a caregiver. Each study enrolled a primary caregiver along with the patient (a study dyad), or involved the caregiver in the CM intervention. Mean patient age ranged from 68 to 83, with seven studies having a patient population averaging 78 years or older. In three studies that required the primary caregiver be a spouse, the mean age range of the spouse caregiver was 71 to 74 years.^{46, 48, 50} In studies that included caregivers other than spouses (most commonly a patient's child), the mean age of caregivers ranged from 44 to 66. Patient eligibility for five of the studies included a diagnosis of Alzheimer Disease,^{44, 48, 50-52} the other seven a diagnosis of dementia (unspecified type).^{45-47, 49, 53-55} One study also included patients with a diagnosis code for memory loss.⁵⁴

CM *interventions* in these studies focused on both patient and caregiver, with the majority emphasizing caregiver support (see Table 6). Intervention components aimed at caregivers included education on problem solving, communication, and coping skills provided through workshops, support groups, and individual counseling sessions. Those CM programs with control over budgeted services had the ability to provide caregivers additional services, such as respite and homemaking. Intervention components aimed at the patient included social and recreational activities, behavioral interventions, pharmacotherapy, and monitoring. Case managers in these studies were generally registered nurses or social workers. Caseloads (reported in only six studies) ranged from 25 to 100, most commonly 50 to 75. Case managers generally had face-to-face contact with patients and/or caregivers, in addition to telephone followup. The time horizon of most studies was 12-24 months, although one study⁴⁸ followed the participants for more than 5 years.

The *comparator* group in 11 of the trials received "usual care", which was defined as customary care through a primary care clinic, or more often through a community agency, without an assigned case manager. One study⁵³ was a head-to-head comparison – case management by an individual nurse case manager compared with case management by a team that included a nurse and a social worker.

Targeted *outcomes* in these studies included patient and/or caregiver health, patient/caregiver satisfaction, quality of care, and resource utilization (see Table 7). Patient health outcomes included measures of dementia-related behavioral problems, cognition and function, quality of life (QOL), and most often (8 of 12 studies) the ability to remain in the home. Caregiver health outcomes included measures of burden, depression, and QOL. Quality of care was measured by receipt of care consistent with clinical guidelines and measures of medication management (cholinesterase inhibitors, antidepressants, and other protocol driven treatments). Resource

utilization measures included ED utilization, hospitalizations, nurse and physician visits, use of community services, and overall costs. Note that nursing home placement was classified as a patient health outcome, due to its strong relationship to quality of life.

The *timing* of a CM intervention can be considered in terms of where the patients are in the course of their disease process. Dementia is nearly always a progressive disorder, with decline in mental function and functional status over time. There is no clinical consensus on when in the course of the illness an intervention like CM would be most effective. As mentioned previously, all the patients in these 12 studies were still living at home. The majority had dementia of mild or moderate severity (for example, mean scores on the Folstein Mini Mental Status Scale of 15-20). Two studies specifically targeted patients with early dementia.^{47, 52}

The *setting* for CM programs varied. Two were aligned with primary care clinics,^{44, 49} but more commonly they were situated within community agencies^{48, 50, 51, 53, 54} or national health care entities.^{45, 46, 52}

In addition to the 12 randomized controlled trials described above, we identified one quasi-experimental clinical trial conducted in the United Kingdom.⁵⁶ Mean age of the participants was 80, and 70 percent were women, the majority of whom lived alone. The comparison group included individuals followed in a similar community program that did not offer CM.

Table 6. Characteristics of case management interventions for patients with dementia

Author Year Quality	Duration (months)	Mode(s) of Contact	Main CM Functions	Contacts (average)	Caseload	Role of Usual Care Provider	Supervision by Physician	Profession	Pre- intervention Training	Use of Protocols or Scripts
Callahan, et al. 2006 Good	12	Home visits, clinic, phone	<ul style="list-style-type: none"> • Clinical monitoring • Counseling and support 	8 face-to-face; 7 calls	75/year	Integrated	Yes	APNs (geriatric NPs)	NR	Yes
Challis, et al. 2002 Poor	12	Home visits	<ul style="list-style-type: none"> • Planning • Caregiver support • Coordination 	17 home visits	20–25	Integrated	Yes	SW	NR	Yes
Chien and Lee 2008 Fair	6	Home visits, support groups	<ul style="list-style-type: none"> • Clinical monitoring • Planning • Counseling and support • Caregiver support • Education 	12 home visits; 12 support sessions	Unclear	NR	Yes	Nurse	Yes	Yes
Chu, et al. 2000 Poor	18	Home visits, phone	<ul style="list-style-type: none"> • Planning • Counseling and support • Caregiver support • Education 	Monthly (increased as needed)	NR	Integrated	Yes	SW	NR	NR
Clark, et al. 2004 Poor	12	Phone	<ul style="list-style-type: none"> • Clinical monitoring • Counseling and support • Education • Coordination 	10/year (based on need)	NR	Integrated	NR	SW	NR	Yes
Eloniemi-Sulkava, et al. 2001 Good	24	Home visits, phone	<ul style="list-style-type: none"> • Counseling and support • Caregiver support • Education 	Varied: 1/month to 5/day	50 (maximum)	Access to the program physician	Yes	RN (public health)	Yes	NR

Author Year Quality	Duration (months)	Mode(s) of Contact	Main CM Functions	Contacts (average)	Caseload	Role of Usual Care Provider	Supervision by Physician	Profession	Pre- intervention Training	Use of Protocols or Scripts
Eloniemi-Sulkava, et al. 2009 Good	20 to 24	Home visits, clinic, phone	<ul style="list-style-type: none"> • Counseling and support • CG support • Education 	Varied: Calls to and from families (range 1-91); Home visits (range 1-43); Office visits (range 1-4)	50-60 couples	Integrated	Yes	APN (3.5 years advanced education and 1 year education in dementia)	Yes	NR
Jansen, et al. 2005 Good	12	Home visits, Phone	<ul style="list-style-type: none"> • Clinical monitoring • Planning • Education • Coordination 	≥2 Home visits; Calls, every 3 months; Time: 11 hrs/yr year (range: 1 – 28 hours)	~ 33 dyads	Integrated	No med management by CMs, presumably PCP	Nurse (specialized in geriatric care)	Yes	Yes
Mittelman, et al. 2006 Good	Unlimited	Clinic, phone, support groups	<ul style="list-style-type: none"> • Counseling and support • CG support • Education • Coordination 	NR	NR	NR	NR	SW ("family counselor")	NR	NR
Newcomer, et al. 1999 Poor	Up to 36	NR	<ul style="list-style-type: none"> • Clinical monitoring • CG support • Education • Coordination 	Minimum of 6 in 4 months	Model A: 1:100; Model B: 1:30	No integration with primary care services	No integration	SW and nurses	NR	NR
Vickrey, et al. 2006 Good	12	Home visits, Phone	<ul style="list-style-type: none"> • Planning • Education • Coordination 	2 home visits; 15 phone calls/year	50 dyads	Integrated (summary assessments sent to PCP)	NR	Primarily SWs	Yes	Yes

Abbreviations: APN, advanced practice nurses; CG, care giver; CM, case management; NR, not reported; NP, nurse practitioner; PCP, primary care provider; RN, registered nurse; SW, social worker.

Key Points

Evidence about Patient-Centered Outcomes

- CM programs that serve patients with dementia and have a duration of no longer than 2 years do not confer clinically important delays in time to nursing home placement (strength of evidence: moderate).
- CM programs that serve patients with dementia reduce depression and strain among caregivers (strength of evidence: moderate).

Evidence about Quality of Care

- CM programs that focus on clinical guideline measures increase adherence to those measures (strength of evidence: low).

Evidence about Healthcare Utilization

- CM does not reduce the use of physician visits for patients with dementia (strength of evidence: moderate).
- CM does not increase acute care hospitalization rates for patients with dementia (strength of evidence: low).
- CM does not provide reductions in health care expenditures for patients with dementia (strength of evidence: moderate).

Evidence about Intervention Characteristics

- CM programs that serve patients with dementia who have in-home spouse caregivers and continue services for longer than 2 years are more effective for delaying nursing home placement than programs providing services for 2 years or less (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Mortality

Ten clinical trials and one quasi-experimental study reported mortality rates. The time frames ranged from 1 to 3 years in all but one study, which followed patients for more than 10 years.⁴⁸ Deaths often were not recorded after nursing home placement, which could bias the reported rates. The death rates varied considerably in the control groups, ranging from 3 percent at 18 months⁵² to 35 percent at 2 years.⁵⁶ There was no trend toward significantly different mortality rates in the groups that received CM.

Patient's Ability to Remain at Home

A total of eight randomized controlled trials and one quasi-experimental trial examined the patient's ability to remain at home. Two clinical trials had sample sizes of more than 100 participants per group.^{48, 50, 55} Mittelman and colleagues⁴⁸ conducted a long-term trial of CM for caregivers of patients with dementia at a single clinical site (New York City). The study had good methodological quality. It began in 1987, and participant accrual extended over 10 years.

Caregivers were required to be the spouse, the primary caregiver, and living with the person with Alzheimer disease. The case managers were family counselors, who interacted primarily with the caregiver, and followed a protocol focused on strategies for coping with stressful situations in the caregiving role. The CM activities extended over the entire duration of follow up (as long as 10 years). There are no other studies of CM in this clinical domain that continued the intervention longer than 2 years.

Over the initial 6 years of follow up in the New York trial, nursing home placement was about 12 percent a year in the control group and about 9 percent a year in the intervention group. By 11 years, about 80 percent of the control group patients and 70 percent of the intervention group patients had either died or moved to a nursing home. The authors estimated that the intervention delayed nursing home placement by an average of about 18 months.

The Medicare Alzheimer's Disease Demonstration and Evaluation (MADDE) was a uniquely large clinical trial.⁵⁵ The MAADE enrolled more than 8,000 volunteers into a prospective randomized trial of CM between 1989 and 1991. The project was conducted in eight states, and the models of CM varied considerably across sites. While the programs included components designed to reduce caregiver stress, the fidelity of the intervention across the multiple sites is unknown. The overall rating of methodological quality is poor. The overall rate of nursing home placement in the MADDE study was 43.5 percent at 3 years of followup. There was no significant difference in this rate between the intervention and control groups. Subgroup analyses examined the case manager's caseload and relationship of the caregiver to the patient (spouse vs. nonspouse). There were no significant effects of receipt of CM on nursing home placement rates in these subgroups.⁵⁷

Six smaller clinical trials examined nursing home placement rates as an outcome measure. Four of these were judged to have good methodological quality. All continued the CM for 2 years or less. Eloniemi-Sulkava and colleagues reported a randomized trial of CM in Finland, with a total of 100 participants enrolled between 1993 and 1995.⁴⁵ Thirty-one percent of patients had moved to nursing homes at the end of 2 years. While the overall rate did not differ between the experimental and control groups, a Cox regression analysis found that patients in the intervention group moved to nursing homes significantly later ($p = 0.04$) than patients in the control group. These results suggest a mild benefit of CM in maintaining patients at home that is not sustained over time. Eloniemi-Sulkava then reported on a second clinical trial, also in Finland, with the participants being recruited in 2004.⁴⁶ This trial included a total of 125 participants and had very similar results to the earlier Finnish trial. The overall rate of nursing home placement was 26 percent at 2 years, with no significant difference in the overall rate between intervention and control groups.

Two other good-quality studies failed to find an effect of CM on rates of nursing home placement. Mittelman⁵⁰ repeated the model of CM that previously had been found to delay nursing home placement when continued long-term.⁴⁸ This replication trial was conducted in the United Kingdom, Australia, and the United States. However, the number of participants was small (between 52 and 54 participants in each country), and the duration of CM was only up to 2 years. The mean time to nursing home placement was 4.1 years in the intervention group and 4.3 years in the control group. Overall nursing home placement rates were lower in the United States than in the other two countries. Callahan⁴⁴ also conducted a trial of CM for patients with dementia. The intervention lasted 12 months and emphasized caregiver skills for coping with bothersome patient symptoms. The nursing home placement rate was 5 percent at 18 months, with no difference between the intervention and control groups.

Three poor-quality studies do not provide evidence that would change the conclusions reached from the studies described above. Chu⁵² reported a small (total of 74 participants) clinical trial that had poor methodological quality. At 18 months of followup, the nursing home placement rate was 28 percent in the control arm. There was no significant difference in placement rate between the intervention and control groups. The authors estimated that CM delayed nursing home placement by an average of 53 days among patients with more severe dementia. In a quasi-experimental trial⁵⁶ conducted in the United Kingdom 43 patients in a CM program were compared with 43 matched controls who did not receive CM. At 2 years, 31 percent of all patients had died. Twenty-one percent of the CM patients had been placed in a nursing home, compared with 33 percent of the patients in the comparison program. Finally, a poor-quality clinical trial of two types of CM in the state of New York included a sub-group analysis of the participants who had dementia.⁵³ Nursing home utilization was nearly identical among patients receiving CM by individual case managers when compared with patients who received CM by a team that included a nurse and a social worker.

Caregiver Health Outcomes

One of the major challenges in caring for patients with dementia is management of problematic behavioral symptoms. Studies of CM have used a variety of methods to measure such symptoms, using two different but related approaches. The first approach is to use a questionnaire such as the neuropsychiatric inventory (NPI) that measures the caregiver's report of the severity of symptoms. The second approach is to assess measures of strain or burden experienced by the caregiver due to performing the caregiving role. Thus, these are measures of the frequency/severity of patient behaviors and the caregiver's stress in dealing with these behaviors. Since the same caregiver usually completes both types of measure, the measurements are not independent. Also, because a variety of different instruments have been used, we will report the trends in such measurements for each study rather than separating out each type of assessment.

Of the 12 randomized trials of CM for dementia, 10 included measures of the caregivers' perceptions of the patients' behaviors. Five of these trials had good methodological quality. The trial reported by Mittelman had both the longest duration of CM and the longest followup period. This study found no difference over time between the CM and control groups in the frequency of problematic behaviors. However, caregiver stress associated with the behaviors was significantly lower in the CM group, and this effect persisted over a 4-year period.⁵⁸ The caregivers in the CM group also reported lower scores on a depression scale, but this difference did not persist beyond 3 years.⁵⁹

Mittelman and colleagues also performed a second randomized trial to replicate the original study.⁵⁰ This trial continued CM for only 2 years. While caregiver burden scores were lower in the CM group, this was not statistically significant. Caregiver depression scores were significantly lower in the CM group during the followup period. While depression scores increased over time in the control group, they decreased over time in the CM group.

Other clinical trials rated as either good or fair quality have had shorter followup periods, but their results generally are consistent with those found by Mittelman.⁵⁰ Callahan⁴⁴ included caregiver assessments of the NPI, a rating of patient depression, and a measure of caregiver stress at 6, 12, and 18 months, although the CM program ended at 12 months. The NPI scores were better in the CM arm at both 12 and 18 months. Measures of caregiver stress also were better in the CM arm at 12 and 18 months. Vickrey⁴⁹ assessed caregiver confidence and quality of life (QOL) after 18 months of CM. Confidence increased modestly in the CM group, but

measures of QOL and caregiver strain did not change. Jansen⁴⁷ conducted a trial of 12 months of CM. This trial found no differences between the CM and control groups in measures of caregiver depression, QOL, or caregiver burden. Chien⁵¹ conducted a fair-quality trial in which patient NPI scores and a caregiver burden measure did not change over 12 months in the control group. In the CM group, both measures significantly improved at 12 months.

Of three other clinical trials rated as poor quality, one⁵⁴ found mild effect of CM on improvement of patient symptoms at 12 months, and one⁵² found no effect on symptoms. Two of these trials^{52, 55} found no effect of CM on caregiver burden or depression. A quasi-experimental trial⁵⁶ also found decreased caregiver burden in the group receiving CM.

Quality of Care Outcomes

The clinical trials of CM for patients with dementia generally have provided only limited data about the effects of the programs on processes of care. However, Vickrey and colleagues⁴⁹ reported a good-quality randomized trial that had adherence to dementia care guidelines as its primary outcome. The study had 23 prespecified dementia guidelines that were included in the clinical protocol for CM. These fell into four clinical domains: assessment, treatment, education/support, and safety. At 18 months, the care was judged to be adherent to a mean of 33 percent of the guidelines in the control group and 64 percent of the guidelines in the CM group. No other studies of CM have examined its effect on guideline adherence.

Resource Utilization Outcomes

Multiple studies have examined the effect of CM on the use of outpatient and inpatient care. In the good-quality trial reported by Callahan,⁴⁴ the frequency of primary care clinic visits was higher in the CM group, but acute care hospitalization rates did not differ between groups. A lower-quality trial⁵⁴ found that the CM group had a higher rate of physician visits but lower rates of ED visits and hospitalizations. In a quasi-experimental trial, both psychiatric and medical hospitalizations were higher in the CM group.⁵⁶

For in-home services, a good-quality trial⁴⁹ found that patients in the CM group had higher utilization of respite and outside caregiver services. Jansen's good-quality study⁴⁷ found no differences in utilization of in-home services between the CM and control groups. A lower-quality trial⁵² also found that the CM and control groups did not differ in the use of in-home services. Another low-quality trial⁶⁰ found increased use of community services among patients receiving CM, but this trial included a financial benefit for these services (in the CM but not the control group), so it is a biased evaluation of this effect. Overall, there is only a small body of evidence about the effect of CM on use of in-home services among patients with dementia.

Three randomized trials, one observational study, and one systematic review have evaluated the effect of CM on costs of care for patients with dementia. All of these studies were short-term, evaluating 1-2 years of followup. Duru⁶¹ examined costs in a good-quality trial evaluating health care, caregiving, and out-of-pocket costs over 18 months. The monthly cost for CM was modest (mean \$118). Total costs (from either a societal or payer perspective) were slightly higher in the control group, but this was not statistically significant. Another good-quality trial also found slightly higher total costs in the control group, but the difference was not statistically significant.⁴⁶ The MADDE trial was a large trial that included an incentive to use home-care services by the CM group. It found that CM had little effect on Medicare expenditures.⁵⁵ In a quasi-experimental study⁵⁶ total costs were higher in the CM group, primarily due to higher utilization of clinic visits and acute care hospitalizations.

Effectiveness of Case Management by Patient Characteristics

As previously described, most of these studies had sample sizes of less than 100 participants in each study arm, which provided little power for sub-group analyses. In two clinical trials, the participants were stratified by severity of dementia. Using time to nursing home placement as the outcome, the differences between intervention and control groups was greatest among those with the greatest severity of dementia, suggesting that these individuals were more likely to benefit from CM.^{46, 52} Another trial⁵⁴ performed regression analyses to see if patient characteristics were associated with utilization outcomes, but these results but found no clear trends.

Effectiveness of Case Management by Intervention Characteristics

The only head-to-head trial comparing two different approaches to CM is an older randomized trial of individual compared with team-based CM.⁵³ This trial tested the hypothesis that a team-based approach would lead to superior outcomes. It had poor methodological quality and had negative findings. For indirect comparisons, the major evidence comes from the Mittelman's good-quality trial conducted in New York City⁴⁸. As described above, this program provided long-term CM (up to 10 years) and specialized in providing services to live-in spouse caregivers. All other CM programs that have been studies served a variety of spouse and nonspouse caregivers and continued services no longer than 2 years. The positive findings in the Mittelman study suggest that long-term specialized CM programs for this clinical problem may have superior success in reducing caregiver depression and stress and in delaying nursing home placement.

Table 7. Characteristics and outcomes of studies of case management for patients with dementia

Author Year Quality	Patient Population	Disease Severity (Usual Care: Intervention)	Setting	Sample Size	Health Outcomes	Patient and CG Experience	Quality of Care	Resource Utilization, Cost
Callahan, et al. 2006 Good	AD patients from a community health center and VAMC; 70% CG living with patient	MMSE (mean): 18.6 vs. 17.5 (Moderate)	Primary care practices	153	↑ Behavioral symptoms = Cognition, function = Time to nursing home placement	↑ CG depression	NR	= Hospitalization rates = Hospital days Physician or nurse visits (<i>more with CM</i>)
Challis, et al. 2002 Poor	Cognitively impaired older adults from U.S., U.K., and Australia; 80% CG living with patient or next door	MMSE (%): <24 = 54 vs. 67	Secondary health care setting	95 dyads	↑ QOL, behavioral symptoms ↑ Patient able to remain at home	↑ CG QOL ↑ CG burden	NR	↓ Cost
Chien and Lee 2008 Fair	Elderly Chinese patients with dementia; 100% CG living with patient	MMSE (mean): 17.3 vs. 17.5 (Moderate)	Dementia center	88 dyads	↑ Behavioral symptoms ↑ Placement rates, number of days in nursing home	↑ CG QOL ↑ CG burden	NR	↑ Service utilization
Chu, et al. 2000 Poor	Individuals with early stage AD; CG living with patient: a) CM= 65%; b) Control= 81%	MMSE (%): ≤23 = 40 vs. 50 ≥24 = 60 vs. 50	Home care program (Canada)	78 dyads	= Cognitive impairment, behavior problems, depression, delayed institutionalization	= CG burden	NR	NR
Clark, et al. 2004 Poor	HMO (Kaiser) clients with dementia	NR	AD center	210	↑ Depression	↑ Satisfaction	NR	↑ Hospital admissions, ED visits

Author Year Quality	Patient Population	Disease Severity (Usual Care: Intervention)	Setting	Sample Size	Health Outcomes	Patient and CG Experience	Quality of Care	Resource Utilization, Cost
Eloniemi-Sulkava, et al. 2001 Good	Patients in the Soc. Insurance Program with dementia 92% CG living with patient	MMSE (mean): 15.3 vs. 14.4 MMSE (%): Mild = 38 vs. 40 Moderate = 38 vs. 24 Severe = 24 vs. 36	Department of Public and General Practice in the University of Kuopio	100 dyads	↑ Delayed institutionalization = Residential placement at 2 years	NR	NR	NR
Eloniemi-Sulkava et al., 2009 Good	AD dementia patients and spouses 100% CG living with patient	MMSE (mean): 14.2 vs. 13.4 CDR (%): Mild = 24.2 vs. 27 Moderate = 54.8 vs. 55.5 Severe = 21 vs. 17.5	Central Union for the Welfare of the Aged in Helsinki	125 dyads	= Residential placement at 2 years	NR	NR	= Cost
Jansen and van Hout, 2005 Good	Community dwelling adults 44% CG living with patient	MMSE (mean): 22.7 vs. 22.0 (Mild)	NR	99	= Patient's QOL	= CG burden, CG QOL, CG depression	NR	NR
Mittelman et al., 2006 Good	CG living with patient and at least one relative living in the area	GDS (%): 4 (Mild) = 31.53 vs. 35.47 5(Moderate) = 37.93 vs. 44.83 6/7(Severe) = 30.54 vs. 19.7	Community-based (NYU Alzheimer's Disease Centers and support groups)	406	↑ Delayed institutionalization = Behavior problems	↑ CG burden, ↑ CG depression	NR	NR

Author Year Quality	Patient Population	Disease Severity (Usual Care: Intervention)	Setting	Sample Size	Health Outcomes	Patient and CG Experience	Quality of Care	Resource Utilization, Cost
Newcomer et al., 1999 Poor	Medicare patients in the MADDE project; 74% CG living with patient	MMSE (%): 0 = 10.0 vs. 10.6 1-5 = 8.1 vs. 8.5 6-10 = 10.5 vs. 10.2 11-15 = 16.9 vs. 15.6 16-20 = 20.6 vs. 21.5 21-25 = 18.0 vs. 18.9 25-30 = 9.4 vs. 8.9 Missing = 6.3 vs. 5.9 (Moderate)	Community-based (8 demonstration sites)	8,138	= Permanent nursing home entry	= CG burden, CG depression	↑ Service use likelihood	= Medicare expenditures
Vickrey et al., 2006 Good	Well-educated, predominantly white Medicare recipients; 70% CG living with patient	Blessed-Roth scale: 6.3 vs. 5.7	Community based within the health care organization	408 dyads	↑ Prescription for Cholinesterase inhibitors or antidepressants	= CG QOL ↑ CG social support	↑ Care quality ↑ Community assistance	= Cost

Abbreviations: AD, Alzheimer's Disease; CG, caregiver; CM, case management; ED, emergency department; GDS, Global Deterioration Scale; HMO, health maintenance organization; MMSE, Mini-mental State Examination; NR, not reported; NYU, New York University; U.K., United Kingdom; U.S., United States; QOL, quality of life; VAMC, Veterans Affairs Medical Center.

↑ Better with case management; = No difference; ↓ Worse with case management.

Case Management for Congestive Heart Failure

Congestive heart failure (CHF) is an illness associated with substantial morbidity and mortality in the elderly and is characterized by frequent exacerbations that make it the leading cause of hospitalizations among Medicare beneficiaries.^{62, 63} Nurse-led interventions, including CM, or commonly used to improve CHF management, with the goals of improving patients' quality of life, maintaining clinical stability, and preventing CHF exacerbations and hospitalization. CM functions used to achieve these goals typically include educating patients to enhance their self-management knowledge and skills; coordinating and facilitating access to multiple clinical providers and services; monitoring clinical parameters; and sometimes adjusting medication regimens and doses.

Description of Studies

We found 10 clinical trials of CM for patients with CHF (see Appendix K); five were rated as good quality,⁶⁴⁻⁶⁸ four fair,⁶⁹⁻⁷² and one poor⁷³ (see Appendix G). Sample sizes of the included trials ranged from 98 to 1049 patients (total N for all studies = 3746). The studies were published between 1993 and 2010.

The *populations* in the 10 trials varied, ranging from members of a large health maintenance organization, who were at low risk for CHF readmission,⁶⁴ to patients with predominantly severe CHF, living in a low-income, urban neighborhood.⁶⁸ Other studies fell within this spectrum, with patients who had moderate (New York Heart Association class II and III) heart failure^{65, 66, 69-73} and were at increased risk for rehospitalization.^{66, 69, 70, 73} Three studies included only patients with systolic heart failure, typically indicated by a left ventricular ejection fraction of less than 35 percent to 45 percent,⁶⁷⁻⁶⁹ while the others included patients with both systolic and diastolic dysfunction.^{64-66, 70-72} The mean age in most studies ranged from 60 to 80.

CM *interventions* varied in nature and intensity (see Table 8). The focus of the interventions ranged from predominantly clinical management – including self-management education, monitoring of clinical parameters, and adjustment of medications – to a more comprehensive CM approach that included a strong element of service coordination and social support. All interventions employed telephone contacts, half included home visitation,^{65-67, 70, 73} and three held face-to-face clinic visits^{65, 66, 68} Case managers were nurses in all interventions; some received supervision from physicians or more senior nursing staff. Most interventions employed protocols or algorithms to guide clinical management of CHF. Most studies evaluated the effect of CM as an isolated intervention, but some included CM as a component of a multidisciplinary team approach to discharge planning and disease management.^{66, 70, 73}

Table 8. Characteristics of case management interventions for patients with congestive heart failure

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contact (Average)	Case- load	Role of Usual Care Provider	Supervision by Physician	Profession	Pre- intervention Training	Use of Protocols or Scripts
DeBusk, et al. 2004 Good	12	Phone	<ul style="list-style-type: none"> • Education • Clinical monitoring • Medication adjustment 	9 hours	NR	Integrated	Yes	Nurses experienced in care management	Yes	Yes
Jaarsma, et al. 2008 Good	18	Home visits, phone, clinic	<ul style="list-style-type: none"> • Education • Clinical monitoring • PS support 	40 hours	NR	NR	No	Nurses specializing in heart failure	Yes	Yes
Kasper et al. 2002 Good	6	Phone, clinic, home visits	<ul style="list-style-type: none"> • Education • Clinical monitoring • Medication adjustment 	8.5 visits (average 57 minutes each)	NR	Approved care plans, notified of test results	Yes	Nurses specializing in heart failure	NR	Yes
Peters-Klimm, et al. 2010 Good	12	Phone, home visits	<ul style="list-style-type: none"> • Education • Clinical monitoring 	5-7 hours	NR	Integrated	No	Nurses	Yes	Yes
Sisk, et al. 2006 Good	12	Clinic, phone	<ul style="list-style-type: none"> • Education • Clinical monitoring 	NR	NR	Integrated	Yes	RNs	Yes	Yes
Laramée, et al. 2003 Fair	3	Phone	<ul style="list-style-type: none"> • Planning • Education • Clinical monitoring • Coordination of services • PS support 	9 calls (5-45 minutes each)	65-89	Integrated for local physicians; others received CM progress reports	No	Cardiology nurse	No	NR
Rich, et al. 1995 Fair	3	Phone, home visits	<ul style="list-style-type: none"> • Education • Clinical monitoring • PS support 	NR	NR	NR	NR	Home care nurse	NR	NR
Rich, et al. 1993 Poor	3	Phone, home visits	<ul style="list-style-type: none"> • Education • Clinical monitoring • PS support 	NR	NR	NR	NR	Home care nurse	NR	NR
Riegel, et al. 2002 Fair	6	Phone	<ul style="list-style-type: none"> • Planning • Education • Clinical monitoring • Coordination of services 	17 calls (16 hours total)	NR	Received calls and progress reports from CM	Supervision by cardiology nurse	RNs	Yes	Yes

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contact (Average)	Case- load	Role of Usual Care Provider	Supervision by Physician	Profession	Pre- intervention Training	Use of Protocols or Scripts
Riegel, et al. 2006 Fair	6	Phone	<ul style="list-style-type: none"> • Education • Clinical monitoring • Coordination of services 	22 calls	NR	Received calls and progress reports from CM	Supervision by cardiology nurse	Nurse	Yes	Yes

Abbreviations: CM, case management; NR, not reported; PS, psychosocial; RN, registered nurse.

The *comparator* group in most studies received usual care without CM. What constituted usual care in most studies was a CHF-specific discharge plan, for patients enrolled during a hospitalization, with outpatient primary care followup that was not standardized. In a study from the Netherlands, outpatient followup care was provided by cardiologists⁶⁵ That study also included a third arm, in addition to CM and usual care, in which patients received nurse-led CHF management that focused on clinical management alone (without coordinating functions) and was less intensive than the CM intervention.⁶⁵

The primary *outcome* in all studies enrolling inpatients was hospital readmission,^{64-66, 69-73} with some studies targeting the composite outcome of readmission or death.^{65, 66, 70} For two studies enrolling outpatients, the primary outcomes were all-cause hospitalizations⁶⁸ and health-related quality of life (QOL).⁶⁷ Other outcomes included patient satisfaction,^{67, 69, 71} patient adherence to self-care plans,^{66, 67, 69} receipt of guideline-recommended CHF medications,^{64, 66, 69} and the overall cost of care.⁶⁹⁻⁷² All studies examined multiple outcomes (see Table 9).

The *timing* and *setting* of CM interventions was in most of the studies related to the principal objective of preventing readmissions among patients hospitalized for CHF. Case managers typically engaged with patients prior to hospital discharge and followed them for 3 to 18 months, depending on the duration of CM stipulated in different study protocols.^{64-66, 69-73} Two studies enrolled outpatients from community medical practices.^{67, 68}

In one good-quality study, the authors reported a conflict of interest, indicating that the Division of Cardiology in which they worked had stock in and was entitled to royalties from the disease management company whose CM intervention they implemented and evaluated.⁶⁶ The company also provided funding for the study, which demonstrated multiple benefits of CM over usual care.

Key Points

- CM improves CHF-related quality of life (strength of evidence: low).
- CM increases patient satisfaction (strength of evidence: moderate).
- CM increases patients' adherence to self-management behaviors recommended for patients with CHF (strength of evidence: moderate).
- CM reduces readmission among hospitalized CHF patients at high risk for readmission (strength of evidence: low).
- CM is more effective in improving outcomes among CHF patients when case managers are part of a multidisciplinary team of health care providers (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Mortality

None of the included studies was explicitly designed to examine the impact of CM on mortality, although three studies included mortality as part of a composite primary outcome measure, usually coupled with rehospitalization.^{65, 66, 70} Two other studies reported mortality rates without explicitly defining it as an outcome.^{64, 71} No study found a significant improvement in either all-cause or CHF-related mortality, but all studies reported lower mortality rates in the CM group compared with controls (RR 0.74 – 0.88). The small number of studies, coupled with heterogeneity of the patient populations, CM interventions, and duration of follow up, preclude

pooling of data to derive a meaningful estimate of potential mortality reduction with CM. The consistency of relative risk across these five studies, however, raises the possibility that CM may provide a survival benefit over usual care for patients with CHF.

Quality of Life

Five studies examined the effect of CM on QOL, using a variety of instruments designed to measure QOL in CHF patients, including the Minnesota Living with Heart Failure Questionnaire,^{66, 68} the Kansas City Cardiomyopathy Questionnaire,⁶⁷ and the Chronic Heart Failure Questionnaire.⁷⁰ Three of these studies also used global measures of functional status that are not specific to CHF: the Medical Outcomes Study SF-36^{67, 68} and the EuroQOL EQ-5D.⁷² Among these five studies, three found significant improvements in CHF-related QOL among patients receiving CM,^{66, 68, 70} one of which also found improvements in overall functional status.⁶⁸ In the other two studies, QOL scores were similar in the CM and control groups, without any trend towards better QOL in either the CM or control groups. In the study showing improvements in overall functional status with CM, they occurred in both physical and emotional domains of functioning.⁶⁸ Notably, in the one study that followed patients beyond the end of the intervention period, functional status declined in the CM group at a rate similar to that in the control group,⁶⁸ suggesting that the benefits of CM may not be durable unless the intervention is continued.

Patient Satisfaction

Three studies reported the impact of CM on patients' satisfaction with care.^{67, 69, 71} Two used general measures of patient satisfaction designed or adapted specifically for their studies and found modest but statistically significant improvements in satisfaction in the CM groups compared with controls.^{69, 71} The third study used the Patient Assessment of Chronic Illness Care (PACIC) instrument and found significant improvements in patient ratings with CM.⁶⁷

Quality of Care Outcomes

Four studies evaluated the impact of CM on indicators of quality of care for CHF. Three examined the use of appropriate pharmacotherapy (e.g., angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers, and beta-blockers for patients with systolic heart failure).^{64, 66, 69} One study showed improvements in the use of recommended medications with CM,⁶⁶ while the other two did not.^{64, 69} Three studies examined adherence to self-care recommendations (e.g., low-sodium diet, monitoring weight).^{66, 67, 69} All three found that patients' adherence to self-management recommendations improved with CM.^{66, 67#249, 69}

Resource Utilization Outcomes

Nine studies reported the impact of CM on all-cause hospitalization rates.^{64-66, 68-73} Results were mixed, with five studies showing lower hospitalization rates with CM^{66, 68, 70, 71, 73} and four showing no difference between CM and controls.^{64, 65, 69, 72, 73} In the four studies showing no difference, the relative rates of hospitalization in CM compared with control groups ranged from 1.02 to 1.12. In one small study, hospitalization rates were lower in the intervention group, but the difference did not reach statistical significance (RR 0.73).⁷³ The other four studies reported significantly lower hospitalization rates with CM,^{66, 68, 70, 71} with relative rates ranging from 0.56 to 0.79, and absolute differences ranging from 19 fewer hospitalizations per 100 patients over a 12-month observation period⁶⁸ to 30 fewer hospitalization per 100 patients over a 3-month period.⁷⁰ Reductions in all-cause hospitalization rates were driven primarily by lower rates of

hospitalization for CHF. Five studies examined the total number of hospital days during the study period, with one reporting fewer hospital days per patient in the CM compared with control group (3.9 vs. 6.2 days over a 3-month period),⁷⁰ and four reporting no difference.^{66, 69, 71, 72}

Five studies estimated the impact of CM on the overall or hospital-related cost of care.^{66, 69-72} Total costs were dominated by the cost of inpatient care, with estimated costs for CM interventions being comparatively small. Accordingly, three studies demonstrating reductions in hospitalization rates with CM also found reductions in cost,^{70, 71} though in one study this difference was not significant.⁶⁶ The two studies that did not find improvements in hospitalization rates also did not find a positive or negative impact of CM on the cost of care.^{69, 72}

We examined study characteristics, patient populations, and intervention components across studies to try to determine which elements might explain the mixed results for the impact of CM on various outcomes. Broadly speaking, three studies can be classified as “negative,” demonstrating no differences between CM and control groups across outcome measures.^{64, 65, 72} Four studies can be considered “positive,” demonstrating improvements in quality of life, hospitalization rates, and/or cost of care.^{66, 68, 70, 71} Finally, two studies can be considered “intermediate,” showing some improvements in patient-reported measures of satisfaction and self-care but not in health outcomes or hospitalization rates.^{67, 69} We excluded one small, poor-quality study from this analysis.

Table 9. Characteristics and outcomes of studies of case management for patients with congestive heart failure

Author Year Quality	Patient Population	NYHA Class ^a	Setting	Sample Size	Health Outcomes	Patient Experience	Quality of Care	Resource Utilization, Cost
DeBusk, et al. 2004 Good	HMO members hospitalized with CHF, at low risk for poor outcomes	I/II: 50% III/IV: 50%	5 hospitals within large HMO (U.S.)	462	=	NR	=	=
Jaarsma et al. 2008 Good	Adults hospitalized with CHF	II: 50% III: 46% IV: 4%	17 hospitals (Netherlands)	1049	=	NR	NR	=
Kasper et al. 2002 Good	Adults hospitalized for CHF, with risk factors for readmission	II: 36% III: 59%	2 university hospitals (U.S.)	200	↑ QOL	NR	↑ Appropriate medications, diet, achieving goal weight	↑ Hospitalizations
Peters-Klimm, et al. 2010 Good	Adults with systolic dysfunction with ≥ 1 hospitalization during prior 2 years	I: 3% II: 65% III: 30% IV: 0.5%	29 small primary care practices (Germany)	199	=	↑ Satisfaction	↑ Self-care	NR
Sisk, et al. 2006 Good	Ethnically diverse, English- and Spanish-speaking adults with systolic dysfunction	I: 19% II: 22% III: 14% IV: 45%	Community general medicine, geriatrics, and cardiology practices (U.S.)	406	↑ QOL	NR	NR	↑ Hospitalizations
Laramée, et al. 2003 Fair	Adults with systolic dysfunction hospitalized for CHF, with risk factors for early readmission	I: 16% II: 43% III: 33% IV: 2%	Single university hospital (U.S.)	287	NR	↑ Satisfaction	↑ Adherence to treatment regimen	=
Rich, et al. 1995 Fair	Patients over 70 hospitalized with CHF, with risk factors for readmission	Mean NYHA class 2.4	Single university hospital (U.S.)	282	↑ QOL	NR	NR	↑ Hospitalizations, hospital days, cost
Rich, et al. 1993 Poor	Patients over 70 hospitalized with CHF, with risk factors for readmission	Mean NYHA class 2.7-3.0	Single university hospital (U.S.)	98	NR	NR	NR	NR
Riegel, et al. 2002 Fair	English- and Spanish-speaking adults hospitalized for CHF	I: 10% II: 18% III: 57% IV: 15%	2 hospitals (U.S.)	358	NR	↑ Satisfaction	NR	↑ Hospitalizations, hospital days, cost
Riegel, et al. 2006 Fair	Hispanic adults hospitalized with CHF	II: 19% III: 46% IV: 35%	2 community hospitals (U.S.)	135	=	NR	NR	=

Abbreviations: CHF, congestive heart failure; HMO, health maintenance organization; NR, Not reported; NYHA, New York Heart Association; QOL, quality of life; U.S., United States. ↑ Better with case management; = No difference; ↓ Worse with case management.

^aTotals may not add to 100% due to incomplete reporting or rounding.

Effectiveness of Case Management by Patient Characteristics

CM is considered to be most appropriate for patients at high risk for poor outcomes. Three studies selected hospitalized patients that had features considered to put them at high risk for readmission.^{66, 69, 70} Two of these studies showed lower hospitalization rates with CM,^{66, 70} while the third demonstrated improvements in patient-reported outcomes.⁶⁹ Four other hospital-based studies enrolled either low-risk⁶⁴ or unselected patients^{65, 71, 72} with CHF. Results were negative in three of these studies^{64, 65, 72} and positive in one.⁷¹

In the three studies enrolling high-risk patients, high risk was defined as having one or more risk factors for readmission. The specific risk factors varied across the three studies. In two of them, a prior history of CHF was considered a risk factor in and of itself.^{69, 70} All three studies included recent hospitalizations as a risk factor, though the specific criteria varied (e.g., four hospitalizations for any reason over the prior 5 years compared with one CHF hospitalization during the prior year). Two studies showing a positive impact of CM on readmission used clinical parameters (e.g., uncontrolled blood pressure) to select high-risk patients,^{66, 70} while the other study, which found an impact on self-care but not on readmission, used mainly social and behavioral factors (e.g., knowledge deficits, potential for lack of adherence, living alone).⁶⁹

Baseline hospitalization rates (those observed in control groups) can also be considered a proxy measure of risk within the sampled populations across studies. We calculated control-group hospitalization rates for each study reporting them and adjusted rates for the duration of followup. Three studies demonstrating a reduction in hospitalization rates with CM^{66, 70, 71} had relatively high baseline rates of hospitalization (1.74 to 2.69 per person per year), while three negative studies^{64, 65, 72} had relatively low rates (0.74 to 0.99 per person per year). A study with an intermediate baseline hospitalization rate (1.47 per person per year) showed no reduction in hospitalizations with CM but improvements in self-care and patient satisfaction.⁶⁹ These findings suggest a pattern of higher success with CM in populations at higher risk of hospitalization. One study did not fit this pattern. In that study,⁶⁸ CM successfully reduced hospitalization rates in a population with a relatively low baseline rate (0.89 per person per year). However, this study was different from others in that patients were not hospitalized at the time of recruitment; the outcome in that study was admission, rather than readmission.⁶⁸

There was no clearly discernible pattern in study outcomes based on whether the study sample included only patients with systolic heart failure, or patients with either systolic or diastolic dysfunction. Likewise, functional status, as measured by New York Heart Association class did not appear to be associated with the impact of CM. The studies with the most class III and IV patients included one positive⁶⁸ and one negative study.⁷²

Few studies specifically targeted vulnerable patient populations. One included predominantly ethnic minority patients with relatively poor functional status in a low-income, urban neighborhood (Harlem, New York City) and found improvements in both QOL and hospitalization.⁶⁸ Another study, however, enrolled Spanish-speaking patients in Southern California, also with poor functional status, and found no improvement with CM.⁷² The authors of this latter study used a CM intervention that was essentially identical to one they used in an earlier study, in which they enrolled predominantly English-speaking patients and found significant reductions in hospitalization rates and cost with CM.⁷¹ Linguistic and cultural factors may explain the difference in success in these two interventions. However, the populations in these two studies also differed in other ways, including more class IV heart failure patients in the unsuccessful study.

In two studies which found CM not to be superior to usual care for any outcome measure, the authors reported that the baseline quality of CHF care may have been sufficiently high such that there was minimal room for the CM intervention to improve quality of care and thereby result in better outcomes.^{64, 65} These studies were conducted in a large HMO (Kaiser Permanente) with a strong quality improvement focus,⁶⁴ and in a group of cardiology practices.⁶⁵ While it is possible that these settings may have resulted in control groups that received higher quality care than in other studies, we did not observe higher rates of appropriate pharmacotherapy in the control groups of those two studies, compared with other studies that reported superior outcomes with CM.

Effectiveness of Case Management by Intervention Characteristics

No studies included head-to-head comparisons of different models of CM. One study compared an intensive CM program to a more basic and less intensive disease management intervention.⁶⁵ Neither the CM nor the less intensive intervention was superior to the control group on any outcomes measures.

Examination of Table 10 reveals few discernible patterns in terms of intervention characteristics that predict successful CM interventions. Interventions that were longer in duration did not produce more positive results, nor did the use of home visits, as opposed to telephone care alone, or the amount of contact time. Only one study reported CM caseloads.⁶⁹ In most studies, CM functions were heavily weighted towards clinical activities, as opposed to coordinating functions; the specific CM functions employed did not track with intervention success, though few studies described CM functions with enough specificity to allow clear delineations in the nature and intensity of those functions. The ability of nurses to adjust medications was present in only two studies, one with negative and one with positive results.^{64, 66}

The degree to which the care delivered by case managers was integrated with patients' usual care providers (usually primary care physicians or cardiologists) was not well described in most studies. Interventions that appeared to include higher levels of integration with usual care providers did not clearly produce better results than others. One study, however, reported significantly lower hospitalization rates among patients whose usual care providers were in the local vicinity where the case manager worked and with whom she therefore had closer contact.⁶⁹ No such improvement in hospitalization rates was observed among patients with nonlocal providers.

The presence of physician supervision of case managers was not clearly associated with better outcomes. Two studies, however, that embedded case managers within teams that included other health professionals (e.g., cardiologist, social worker, dietitian), demonstrated better outcomes across multiple domains in the intervention compared with control group.^{66, 70} Preintervention training for nurse CMs, and care protocols to guide clinical management, were not more prevalent in successful compared with unsuccessful CM interventions.

Consistency with Previous Systematic Reviews

We found no prior systematic reviews examining the effect of CM, specifically, among patients with CHF. Five reviews examined "care management"⁷⁴ and "disease management,"⁷⁵⁻⁷⁸ interventions. These reviews included many of the studies included in our review but also other studies of primarily nurse-led interventions that did not meet our criteria for being considered CM. There was significant heterogeneity in the nature and duration of the interventions examined in these reviews. Nevertheless, meta-analysis demonstrated a significant reduction in

hospitalization rates with disease management in three of the reviews,⁷⁵⁻⁷⁷ and a reduction in all-cause mortality in two reviews;^{75, 77} all reviews included largely the same group of individual studies. Gohler et al. also conducted a meta-regression of 36 disease management studies and found that rehospitalization rates were significantly lower in interventions that involved multidisciplinary teams, and in those that included face-to-face contact with patients, as opposed to telephone contact alone.⁷⁵ Windham, et al. conducted a qualitative analysis of differences in outcomes among studies of care management for CHF.⁷⁴ They found that 15 of 32 studies demonstrated improved outcomes with care management, and 15 showed nonsignificant trends towards improvement. Common elements observed in successful interventions included more frequent clinical monitoring, collaboration between a physician and nurse in delivering the intervention, and patient education in self-management skills.⁷⁴ Yu, et al. similarly reviewed 21 clinical trials of CHF disease management interventions and compared and contrasted “effective” and “ineffective” interventions. They found that effective interventions were characterized by: an in-hospital phase of care, intensive patient education, self-care supportive strategy, optimization of medical regimen, and ongoing surveillance and management of clinical deterioration.⁷⁸

Case Management for Patients with Diabetes Mellitus

Diabetes mellitus (DM) is a significant health problem, currently estimated to affect 26 million Americans and approximately 27 percent of adults over age 65. The prevalence of diabetes continues to rise, as do the associated increased risks of cardiovascular disease, end stage renal disease, neuropathy, and retinopathy. Considerable healthcare resources have been devoted to seeking mechanisms to optimize care for diabetic patients as a strategy to diminish the morbidity and mortality associated with this chronic health condition. Diabetes is especially complex in that its management requires avid and persistent participation from both the provider and patients, the latter of whom must alter their habits (diet and exercise) on a daily basis and often incorporate a complex regimen of medications. CM may offer new mechanisms to aid both patients and providers in DM care. The ability of case managers to work with patients to improve education and individual goal setting may positively impact patients’ understanding of their diabetes and their self-directed care activities. Case manager involvement may also aid providers via improved tracking and implementation of screening tests. Although the overall functional status of many patients with diabetes is relatively good, the rationale for case management is that they need assistance and training to improve self-management skills and to improve the overall coordination of their health care.

Description of Studies

We identified seven clinical trials and three observational studies of adults with diabetes (see Appendix L). Of the clinical trials, one was rated good quality⁷⁹ and six were rated fair quality⁷⁹⁻⁹¹ (see Appendix G). All seven trials were conducted in the United States and published between 2002 and 2009. Sample sizes ranged from 147 to 1,665 participants (total N = 3,776); notably, the majority of these studies were relatively small, with five of the seven having fewer than 400 participants.^{79, 80, 84-86, 90, 91} Of the three observational studies, two were rated fair quality^{92, 93} and one was rated good quality.⁹⁴ All three observational studies utilized a retrospective cohort design, were conducted in the United States, included a total patient population of greater than 1000 (range 1076 to 5925), and were published between 2005 and 2009. Study duration ranged

from 12 months to 5 years. Only one study examined outcomes at 5 years,⁸⁹ however, and nine of the 10 studies limited their followup or retrospective analysis to 2 years or less.

The *populations* examined by these 10 studies varied significantly. The mean age of participants ranged from 48 to 71. There was notable heterogeneity in racial/ethnic backgrounds, as some trials limited their patient populations to African Americans,^{81, 83} American Indians/Alaskan Natives,^{92, 93} or Latinos.⁸⁰ Five trials examined only individuals with type II diabetes.^{79-82, 84, 86, 90, 91} These trials also exhibited different levels of complexity defined by different characteristics, including differences in disease severity. Mean hemoglobin A1c (HbA1c) ranged from 7.4 to 9.7 percent; four of the seven trials reported mean HbA1c of 8.5 percent or greater.^{80, 83, 85, 86, 91} Four trials reported duration of diabetes in their populations, which ranged from 7 to 12 years.^{79, 80, 83, 85, 86, 90, 91} Population complexity was also compounded by differing degrees of socioeconomic disparity. Five of the seven clinical trials particularly included populations with indicators of lower socioeconomic status.^{80-84, 86-89, 91} All five of these trials documented poverty or low annual income in the majority of participants. Four studies documented a low educational level in the majority or a broad percentage status.^{80-82, 84, 91} One of the six trials documented that a large percentage utilized medical assistance programs or were uninsured.⁸³

CM *interventions* demonstrated similarities and discrepancies among the studies (see Table 10). The intensity of the CM intervention was potentially similar for seven of the 10 studies, in that face-to-face interaction was the primary mode of CM delivery, supplemented with telephone contact.^{79, 80, 83, 85, 86, 90, 91, 93, 95} One trial utilized only face-to-face interactions^{81, 82, 84} and one exclusively telephone interactions.⁸⁷⁻⁸⁹ Unfortunately, very few trials reported adherence to the CM intervention, or the number of case manager interactions/visits, making true intervention intensity difficult to assess. Case managers in each study were responsible for a variety of patient-related activities, from initial assessment and development of a treatment plan, to resource referral, to clinical care activities such as glucose monitoring. Case managers presumably had varying levels of autonomy with which to achieve their roles, although four of the 10 studies reported using a protocol or best practices script. Case managers for the included studies were primarily nurses, although some were registered dietitians^{79, 86, 90, 91}, or social workers.⁹⁵

Table 10. Characteristics of case management interventions for patients with diabetes

Author Year Quality	Duration	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Case- load	Role of Usual Care Provider	Supervision by Physician	Profession	Pre- intervention Training	Use of Protocols or Scripts
Babamoto, et al. 2009 Fair	12 months recruitment, 6 months followup	FTF visits and phone	<ul style="list-style-type: none"> Assessment Develop treatment plan Resource referral 	NR	53 patients per CM	Integrated	NR	RN	NR	Yes (protocol)
Medi-Cal 2004 Fair	36 months	FTF visits and phone	<ul style="list-style-type: none"> Identified barriers Develop treatment plan Education 	NR	NR	Integrated	Yes	RN or RD	NR	Yes (protocol and algorithm)
Gary, et al. 2003 Fair	2 years enrollment, 2 years followup	FTF visits with phone	<ul style="list-style-type: none"> Educate Resource referral Feedback to MDs 	NR	NR	Integrated	Yes	RN	NR	NR
Gary, et al. 2004; Gary, et al. 2005; Gary, et al. 2009 Fair	20 months enrollment, 30 months followup	FTF visits	<ul style="list-style-type: none"> Assessment Develop treatment plan Titrate insulin 	NR	269	Integrated	NR	RN	6 weeks	NR
Krein, et al. 2004 Fair	18 months	FTF visits and phone as needed	<ul style="list-style-type: none"> Monitor home glucose and BP Reminders about screening tests Med adjustment 	Goal of 3/year	120	NR	NR	NP	2-day training	Yes (algorithm)
Shea, et al. 2002; Shea, et al. 2006; Shea, et al. 2009 Fair	2 years initially; 5 years overall	Exclusively phone	<ul style="list-style-type: none"> Monitoring blood glucose and BPs Confer with endocrinology if med adjustment felt needed Resource referral 	NR	200	Integrated	Yes	Unclear	NR	NR
Wolf, et al. 2004; Wolf, et al. 2007 Good	12 months	FTF and phone	<ul style="list-style-type: none"> Review labs Establish and adjust goal Education 	NR	72	NR	Yes	RD	NR	NR

Abbreviations: BP, blood pressure; CM, case management; FTF, face-to-face; MD, medical doctor; NP, nurse practitioner; NR, not reported; PRN, as needed; PS, psychosocial; RD, registered dietitian; RN, registered nurse; SW, social worker.

The *comparator* group for each study was defined as usual care, which uniformly referred to care by a patient's primary care or usual care provider. Patients in the control groups did not have access to the specialized case management programs.

Targeted *outcomes* in these studies included patient health, patient satisfaction, quality of care, and resource utilization (see Tables 11 and 12). Patient health outcomes included hard endpoints (mortality, QOL) as well as a number of intermediate measures such as HgA1c, cholesterol management, blood pressure control, and weight/body mass index (BMI) among others. Quality of care measures included eye and foot examinations, medication adherence, and glucose self-monitoring. Resource utilization measures included ED utilization, hospitalizations, primary care utilization, and a cost analysis.

The *timing* of the CM intervention was mentioned by only one trial, which limited their population to individuals with a new diagnosis of type II diabetes (within 6 months of enrollment).⁸⁰

The *settings* for the CM interventions were similar across studies. In eight of the 10 studies, the CM intervention was conducted in an outpatient clinic setting.^{79-82, 84, 86, 90, 91, 93, 95} in the remainder of the studies, the location of the CM intervention was unclear.

Key Points

- CM is not effective at improving mortality among adults with diabetes (strength of evidence: low).
- CM is not effective at improving glucose management among diabetic adults (strength of evidence: moderate).
- CM is not effective at improving measures of lipid management, blood pressure management, or weight/BMI in patients with diabetes (strength of evidence: moderate).
- CM is not effective at improving measures of QOL in adults with diabetes (strength of evidence: low).
- CM is not more effective at improving health outcomes among particular patient subgroups, including racial, ethnic, and diabetic-type compared with the diabetic population overall (strength of evidence: low).
- CM is not effective at improving the quality of care measure of regularity of eye examinations (strength of evidence: low).
- CM is effective at improving other quality of care measures including medication adherence and adherence to recommended screening tests (strength of evidence: low).
- CM is not effective at improving resource utilization outcomes among adults with diabetes (strength of evidence: low)

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Mortality

One study, a clinical trial rated as fair quality, examined 5-year mortality in adults with diabetes who were exposed to a CM intervention.⁸⁹ The duration of the intervention was 2 years, but total followup was 5 years. This study did not find a mortality benefit from this CM intervention after 5 years (hazard ratio for mortality 1.01, 95% CI 0.82 to 1.24).

Quality of Life

Two clinical trials examined differences in QOL among adults exposed to CM.^{80, 90} These trials utilized similar CM intervention techniques (face-to-face as well as telephone) and had similar overall duration. Babamoto, et al.⁸⁰ examined self-reported QOL and found no significant improvement or difference between intervention and control. Wolf, et al.⁹⁰ examined QOL outcomes via changes in the short-form 36 (SF-36); they report observing differences seven of nine SF-36 categories between intervention and control groups, but p values and direction of those differences were not reported.

Changes in Hemoglobin A1c

All of the seven clinical trials examined differences in glucose control over time, measured by HgA1c.^{79, 82, 83, 85, 88-91} (See table 11). Two fair-quality trials^{88, 89, 91} found a statistically significant decline in HgA1c in the CM group compared with usual care. One trial, also rated as fair quality, provided information on within-group change in HgA1c over time but did not perform statistical comparison between groups.⁸⁰ This study found that HgA1c decreased from 8.5 percent to 7.4 percent in the CM group but did not significantly decrease in the usual care group (7.5 percent to 7.7 percent), suggesting a possible benefit of CM for HgA1c improvement in this study. Four trials, three fair quality and one good quality, found no significant difference between CM and usual care groups.^{82, 83, 85, 90} Wolf, et al.⁹⁰ did initially note a statistically significant decrease in HgA1c at 4 months ($p=0.008$), but that difference did not persist over time (no significant difference between groups at 8 months or 12 months followup). The three trials which suggested improvement in HgA1c with CM intervention did not differ significantly in terms of intervention setting or duration from those trials which did not show a difference. Of note, the Idea-tel trial (rated fair quality), which did suggest improvement in HgA1c, was the largest included trial ($n=1,665$) and provided the longest followup (5 years total) but also utilized a very different CM intervention compared with all other included studies (tele-health intervention only).^{88, 89} One of these studies also included specifically low socioeconomic status participants,⁹¹ while the other limited its patient population to Latino individuals with type II diabetes.⁸⁰

Three observational studies also examined changes in HgA1c between CM and control groups. Two of these three studies, one rated good quality and one rated fair quality, found improvement in HgA1c among individuals exposed to CM.^{92, 93, 95} The third study did not find improvement in HgA1c among those individuals who were followed by a nurse care manager compared with those followed by their primary care provider alone.⁹²

Additional Intermediate Health Outcomes

Six clinical trials and one observational study examined a cholesterol-related outcome – change in total cholesterol, triglyceride levels, low-density lipoprotein (LDL) cholesterol, or high-density lipoprotein (HDL) cholesterol.^{23, 82, 83, 85, 88-91} (See table 12). Of these, the vast majority identified no improvement in these measures of cholesterol management in the CM arm compared with usual care. One study^{88, 89} did note improvement in LDL with CM, but this trial was methodologically quite different from the other studies, both in its longer duration and its intervention technique as described above. One trial⁸³ identified a significant improvement in triglycerides among adults exposed to CM; this study was conducted in a very specific patient population (African-American, patients with type II diabetes living in an inner-city environment) and did not identify improvement in LDL or HDL with CM.

Changes in blood pressure were examined as changes in systolic blood pressure (SBP) and diastolic blood pressure (DBP). (See table 12). Five trials (all fair quality) examined changes in SBP and DBP and the majority (4 of the 5) identified no benefit or excess harm of CM for SBP management.^{82, 83, 85, 91} The one positive trial^{88, 89} again differed significantly methodologically from the other studies.

Four trials examined changes in BMI, and none identified a benefit of CM.^{80, 82), 83, 91} (See table 12). Two trials, one good quality and one fair quality, examined change in weight and describe discordant results.^{90, 91} One trial (rated as fair quality) identified no significant difference in weight among those who received CM,⁹¹ while the other trial (rated as good quality) did identify benefit ($p < 0.001$).⁹⁰ The latter was also the only study to examine changes in waist circumference, and a significantly greater decrease in waist circumference in the CM group was also observed ($p < 0.001$).⁹⁰ The study by Wolf, et al.⁹⁰ differed from the negative trial in its somewhat shorter followup time (12 months vs. 36 months), but both trials utilized face-to-face and telephone CM techniques in the outpatient clinic setting. While weight and BMI are not the same, they are certainly related. In total, five trials found no benefit in BMI/weight adjustment with CM intervention, while one did find a benefit.

Babamoto, et al.⁸⁰ examined changes in exercise frequency and fruit/vegetable intake among diabetic adults who were exposed to a CM intervention. While they found no significant difference between intervention and control groups for exercise frequency, they did find that individuals in the CM group had significantly higher fruit and vegetable intake ($p < 0.05$). Gary, et al.⁸³ examined a dietary score as well as a physical activity index; there was no significant difference between groups for either of these outcomes. The California Medi-Cal Type 2 Diabetes study^{86, 91} evaluated the risk of development of retinopathy, and found that those who received usual care were at greater risk (OR 5.35, $p = 0.034$) compared with their CM intervention counterparts.⁸⁶

Patient Satisfaction

Krein, et al. assessed “general satisfaction” of individuals who received CM compared with usual care and found significantly greater satisfaction among patients in the CM group ($p = 0.04$).⁸⁵

Quality of Care Outcomes

Quality of care was examined via process measure outcomes. Process measure outcomes include those tests or examinations which are recommended to help curb disease severity or to follow/manage other disease manifestations. In the case of diabetes, this ranged from eye examinations to screen for nephropathy, microalbuminuria testing to screen for nephropathy, and peripheral nerve testing to screen for neuropathy to ensuring appropriate medication regimens such as aspirin and angiotensin converting enzyme inhibitor use. The majority of the available quality of care outcomes were examined by a single study. The one outcome which was examined by two studies was eye examinations.

Two trials, both rated as fair, examined the frequency of patient receipt of the recommended dilated eye examinations among diabetic adults.^{85, 93} One observed no significant difference in rates of eye exams between groups ($p = 0.11$).⁸⁵ The other, an observational study, also rated as fair, examined this outcome as well and found improved regularity of dilated eye examination among individuals who were exposed to CM intervention ($p = 0.001$).⁹³

The same two studies examined medication use/prescription. Krein, et al.⁸⁵ observed aspirin and statin use in CM compared with usual care and found no significant difference between

groups for either medication ($p=0.15$ and $p=0.20$ respectively). Wilson, et al.⁹³ observed a significant increase in the likelihood of aspirin prescription among patients exposed to CM ($p=0.0001$), but there was no significant difference in treatment patterns for utilizing angiotensin blocking agents (angiotensin converting enzyme inhibitors or angiotensin receptor blockers) or lipid-lowering therapy.

One trial, rated as fair quality, examined adherence with recommended medications.⁸⁰ They found that patients in the nurse care management intervention group showed significant improvement in medication adherence compared with the usual care group ($p<0.05$).

One observational study (rated as fair quality) examined several additional measures which were not examined by any of the other included studies. Wilson, et al.⁹³ found that individuals with diabetes who received CM were significantly more likely to receive dietary instruction from a dietitian ($p=0.0001$), to self-monitor their blood glucose ($p=0.0001$), to have dental examinations ($p=0.0002$), to have a comprehensive foot examination ($p=0.005$), and to have nephropathy screening performed ($p=0.002$). They also examined utilization of recommended medications in diabetic adults. The overall quality of this evidence was low, and suggested that CM does not benefit regularity of eye examinations among adults with DM, but may potentially benefit other quality of care outcomes including use of preventive screening tests.

Resource Utilization Outcomes

Resource utilization outcomes can include analysis of trends or frequency with which the examined population utilized the health care system. In the case of diabetes, CM might be expected to potentially improve hospitalizations, both via influence on direct diabetic etiologies for admission (e.g. hypoglycemia, hyperglycemia), and via improvement in diabetes related illness such as cardiovascular disease and peripheral neuropathy, among others. CM could similarly potentially influence ED visits, primary care provider appointments, and even overall cost of health care. Four of the 10 included studies examined health resource utilization outcomes among diabetic patients exposed to CM interventions.^{80, 81, 85, 90}

Two trials^{80, 82}, both rated as fair quality, examined differences in rates of ED utilization; these two studies varied significantly by CM intervention strategy and patient population and described somewhat discrepant results. (See Table 11). Babamoto, et al. included only diabetic adults of Latino ethnicity with new onset diabetes, while Gary, et al. included only African-American adults with type II diabetes living in an inner-city area.^{80, 82} In comparison, Gary, et al.⁸² utilized a mixed intervention team including a case manager and a community health worker (CHW). Babamoto, et al.⁸⁰ found that patients in the usual care group experienced an increase in ED visits as compared with the CM group ($p<0.05$); Gary, et al.⁸² observed significantly fewer ED visits or hospitalizations in the CM and CHW group at 24 months ($p<0.05$, relative risk 0.77, 95% CI 0.59 to 1.0 with 23 percent rate of reduction), but at 36 months significant results were found to be dependent only on the intensity of the CHW intervention.

Two trials^{82, 85} examined differential rates of hospitalizations. Again, the intervention strategy and subgroup population of Gary, et al. differed considerably from that of the other study.^{82, 85} Krein, et al.⁸⁵ did not restrict their population by race or diabetes subgroup. Despite these design differences, results of these two studies for this outcome were similar. Krein, et al.⁸⁵ identified no significant difference in rates of hospitalizations at the VAMC for participants in the CM group, while Gary, et al. observed that the CM intervention alone did not significantly alter hospitalization rates at 36 months.

One fair-quality trial by Krein, et al.⁸⁵ examined changes in rates of primary care provider visits. They identified no significant difference between CM and usual care groups for primary care provider visit frequency.

One good-quality clinical trial examined several aspects of cost as well as prescription medication utilization.^{79, 90} Wolf, et al. found that adults in the CM intervention arm were prescribed fewer medications overall compared with adults who received usual care ($p=0.03$).⁷⁹ These adults did not experience decrease in overall prescriptions cost, however. They also observed reduced mean overall health care costs, but no significant difference in cost of ER visits for patients in that intervention arm.

Table 11. Characteristics and outcomes of studies of case management for patients with diabetes

Author Year Quality	Patient Population	Setting	Sample Size	Health Outcome: Lower HgA1c	Resource Utilization (Hospitalizations/ ER Visits)	Quality of care (Eye Examinations/ Medication Adherence)
Babamoto, et al. 2009 Fair	Age 18+, inner-city Latinos with incident DM-II	Primary care clinic	318	↑ (statistical analysis not provided)	↑ ER visits	↑ Medication adherence
Medi-Cal 2004 Fair	Age 18+ with DM-II, with HgA1c >7.5%	Primary care clinic	362	↑	NR	NR
Gary, et al. 2003 Fair	Age 35-75, inner-city African- Americans with DM-II	Outpatient clinic	186	=	NR	NR
Gary, et al., 2004; Gary, et al., 2005; Gary, et al., 2009 Fair	Age 25+, inner-city African- Americans with DM-II	Primary care clinic	542	=	↑ Hospitalizations	NR
Krein, et al. 2004 Fair	Age 18+; prescription for oral hypoglycemic, insulin, or glucose monitoring in year prior with HgA1c >7.5%	NR	246	=	= Hospitalizations	= Eye exams
Shea, et al., 2002; Shea, et al., 2006; Shea, et al., 2009 Fair	Age 55+, on Medicare, with DM, living in underserved area	2 remote telephone bank locations	1,665	↑	NR	NR
Wolf, et al., 2004; Wolf, et al., 2007 Good	Age 20+, DM-II, BMI ≥27	Outpatient clinic	147	=	= ER visits	NR

Abbreviations: BMI, body mass index; DM, diabetes mellitus; ER, emergency room; HgA1c, glycated hemoglobin; NR, not reported.

↑ Better with case management; = No difference; ↓ Worse with case management

Table 12. Intermediate health outcomes among trials of case management for diabetes^a

Author Year Quality	Lipids^b	Blood Pressure^b	Body Mass Index^b	Weight/Waist^b
Babamoto, et al. 2009 Fair	NR	NR	BMI: =	NR
Medi-Cal 2004 Fair	LDL: = HDL: = TC: = Trig: =	SBP: = DBP: =	BMI: =	Weight: =
Gary, et al. 2009 Fair	LDL: = HDL: = TC: =	SBP: = DBP: =	BMI: =	NR
Krein, et al. 2004 Fair	LDL: =	SBP: = DBP: =	NR	NR
Shea, et al. 2006; Shea, et al. 2009 Fair	LDL: ↑ (p<0.05)	SBP: ↑ (p=0.024) DBP: ↑ (p<0.001)	NR	NR
Wolf, et al. 2004 Good	LDL: = HDL: = TC: = Trig: =	NR	NR	Weight: ↑ (p<0.001) Waist: ↑ (p<0.001)
Dorr, et al. 2005 Good	LDL: =	NR	NR	NR
Curtis, et al. 2009 Fair	NR	NR	NR	NR
Wilson, et al. 2005 Fair	NR	NR	NR	NR

Abbreviations: BMI, body mass index; DBP, diastolic blood pressure; HDL, high-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol; NR, not reported; SBP, systolic blood pressure; TC, total cholesterol; Trig, triglycerides.

^aThis table reports those health outcomes that were examined by two or more trials.

^b=: No difference between CM and usual care; ↑: CM superior to usual care; ↓: CM inferior to usual care.

Effectiveness of Case Management by Patient Characteristics

Several studies examined specific patient subgroups of people with diabetes. By far the most common sub-population examined was that of type II diabetic patients (examined by five of 10 studies).^{79-84, 90, 91} These five studies (four rated as fair and one rated as good) examined two of the same patient health outcomes: HgA1c and BMI. The results of these five studies, however, did not differ significantly from the three studies which did not examine this subgroup.

Two studies limited their patient populations to urban, inner-city patient populations,^{80, 83} and two other clinical trials examined CM among African-American adults with diabetes.⁸²⁻⁸⁴ All four of these studies were rated as fair quality, and all examined BMI as an outcome. CM was not associated with improved BMI in any of these studies. The two clinical trials of African-American adults with diabetes⁸²⁻⁸⁴ also did not find improvement with CM in other physiologic outcomes (HgA1c, SBP, HDL cholesterol). Two observational studies limited their populations to American Indians/Alaskan Natives with diabetes.^{92, 93} These studies both examined change in HgA1c, but identified discordant results; Wilson, et al.⁹³ observed significant improvement in HgA1c among individuals who received the CM intervention (p<0.006) while Curtis, et al. did

not. Two other patient populations (Latinos and adults living in under-served areas) were each examined by only one study.^{80, 87-89} Overall, there was minimal evidence suggesting that CM is more effective for improving outcomes for diabetes in any subpopulation.

Effectiveness of Case Management by Intervention Characteristics

Only one observational study evaluated different CM strategies head-to-head.⁹² This study included three intervention arms which differed in intensity: usual care by primary care provider alone (least intensive), primary care provider and nurse case manager combined intervention (intermediate intensity), and primary care provider and nurse case manager intervention which allowed case managers to alter medications (most intensive). Interpretation of results from this study is challenging because of the distribution of patients among the study arms. Although the total population for this study was large (n=2300), the vast majority (98 percent) of participants were in either the least intensive (usual care) or intermediate intensity CM arm, with only 60 patients included in the high intensity CM group. Because of the small sample size in the high intensity arm, the precision of the results is low. This study identified no benefit of CM for HgA1c between arms, but did observe a statistically significant increase in hypoglycemic events in the most intensive arm (p=0.035). However, this is based upon a single hypoglycemic event in the most intensive arm.

CM strategies employed by the included studies overall were quite variable (see Table 10). There were no consistent similarities in CM strategies among trials with positive results. Only one trial⁸⁷⁻⁸⁹ reported results which consistently showed a benefit of CM in diabetes (to improve HgA1c, LDL, and blood pressure); that trial, rated as fair quality, was the only trial to utilize solely telephone interactions between case manager and participant. One other trial which identified a significant improvement in HgA1c with CM utilized a strategy of both face-to-face and telephone interactions by care managers; of note, this trial only identified a positive result for HgA1c improvement but did not find that CM improved other health outcomes.⁹¹

Consistency with Previous Systematic Reviews

In considering the potential impact of CM on care for patients with diabetes, we examined six systematic reviews⁹⁶⁻¹⁰⁰ on this topic. None of these reviews used definitions of CM that were consistent with those used in our review.

Case Management for Patients with Cancer

The goals of CM for patients with cancer are generally to support and navigate patients through intensive and complex treatment regimens (e.g., surgery, chemotherapy, and radiation); to manage symptoms (e.g., pain, dyspnea, nausea, and fatigue) associated with cancer or its treatment; to maintain patients' physical, mental, and emotional well-being and independence in the context of serious illness and often debilitating treatment; and to help patients, families, and caregivers plan for and cope with the psychosocial and emotional burden imposed by the diagnosis, treatment, and prognosis of cancer. Many CM activities in the setting of cancer care overlap with other interventions such as hospice and palliative care services. What differentiates CM is that comprehensive care coordination is usually the primary focus, while hospice and palliative care interventions tend to focus primarily on symptom management.¹⁰¹

Description of Studies

We found six clinical trials of CM for patients with cancer (see Appendix M). Of these, four were rated fair quality^{14, 102-104} and two poor quality^{105, 106} (see Appendix G). Sample sizes of the included trials ranged from 203 to 335 patients (total N for all studies = 1406). The earliest included study was published in 1989 and the most recent in 2006.

The *populations* in which CM interventions were tested varied substantially across studies. Two studies evaluated CM for patients with breast cancer,^{103, 106} two for patients with lung cancer,^{104, 105} and two for patients with a variety of cancer types.¹⁰² Patients ranged in age from 21 to 85 years old, although the mean ages reported by the majority of the studies ranged from 55 to 72 years old. One study recruited only patients meeting criteria for being homebound.¹⁰⁵ None of the other six studies explicitly targeted vulnerable patients with complex care needs (e.g., disabled, mentally ill, socioeconomically disadvantaged) beyond the vulnerability and complexity inherent in undergoing treatment for and coping with cancer. Some studies were conducted in patient populations with high levels of comorbidity¹⁰⁴ or low socioeconomic status.¹⁰²

CM *interventions* across the six studies shared some common elements but varied in both content and implementation (see Table 13). In all six studies, case managers performed a variety of functions, including developing management plans; addressing the psychosocial and emotional needs of patients and their families or caregivers; educating them about cancer and its treatment; assessing, monitoring, and treating symptoms; and coordinating care and making referrals. CM functions were deployed mainly through home visits, face-to-face encounters in a clinic setting, and telephone calls. The duration of CM interventions, as implemented in each trial, ranged from 3 months to 2 years. The intensity of CM also varied, from multifaceted and comprehensive CM that included home visits, telephone calls, and accompanying the patient to doctor visits¹⁰³ to lighter interventions involving primarily telephone calls to evaluate and coordinate simple care needs.¹⁴ In most cases, case managers were nurses with specialized training in cancer care. Although protocols and care scripts were used in some interventions, case managers had the flexibility to individualize care according to specific patient needs in all studies.

Table 13. Characteristics of case management interventions for patients with cancer

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Case- load	Role of Usual Care Provider	Supervision by Physician	Profession	Pre- intervention Training	Use of Protocols or Scripts
Engelhardt, et al. 2006 Fair	6	In-person (clinic NR)	<ul style="list-style-type: none"> • Planning • PS support • Coordination 	6	NR	NR	NR	RN, NP, or SW	Yes	Yes
Goodwin, et al. 2003 Fair	12	Home visits, clinic, phone	<ul style="list-style-type: none"> • Planning • Education • PS support • Coordination 	24	50-60	Integrated	NR	RNs with prior CM experience	Yes	Yes
Moore, et al. 2002 Fair	12	Home visits, phone	<ul style="list-style-type: none"> • Education • Clinical monitoring • PS support • Coordination 	8	NR	Assessed by CMs for complication s	NR	Oncology APNs	NR	Yes
Mor, et al. 1995 Fair	6	Phone, clinic	<ul style="list-style-type: none"> • Clinical monitoring • Education • PS support • Coordination 	36 (average 23 minutes per contact)	50	Integrated	Yes	Clinical nurse specialists in lung cancer	Yes	Yes
McCorkle, et al. 1989 Poor	6	Phone, home visits	<ul style="list-style-type: none"> • Planning • Education • Clinical monitoring • Coordination 	7 (average 34 minutes per call)	NR	Referred patients to program	NR	NR	NR	NR
Ritz, et al. 2000 Poor	24	Phone, home visits, clinic	<ul style="list-style-type: none"> • Planning • Education • Clinical monitoring • Coordination 	23 hours per patient	50-60	Integrated	NR	APNs	NR	NR

Abbreviations: APN, advanced practice nurses; CM, case management; NP, nurse practitioner; NR, not reported, PS, psychosocial; RN, registered nurse; SW, social worker.

The *comparator* group in most CM trials was described as usual, standard, or conventional medical care. In most studies, the nature of usual care was not explicitly described. One study of patients undergoing lung cancer treatment in the United Kingdom described usual care as outpatient visits in the post-treatment period and then at 2-3 month intervals.¹⁰⁴ Another study of patients with lung cancer compared CM both to a “standard” home care intervention carried out by a multidisciplinary team (without a case manager) and to usual outpatient care.¹⁰⁵

Targeted *outcomes* in CM trials (see Table 14) included health outcomes such as QOL, functional status, cancer-related symptoms, and survival;^{14, 103-106} patient and caregiver satisfaction with care;¹⁰²⁻¹⁰⁴ receipt of specific treatments and services considered to represent high-quality cancer care;¹⁰²⁻¹⁰⁴ utilization of resources not considered to represent high-quality care (e.g., hospitalization, ED visits);^{14, 104, 105} and the overall cost of care.^{102, 104, 106}

The *timing* of CM interventions varied across studies. In four studies, case managers primarily supported and coordinated the care of patients undergoing treatment for cancer;^{14, 103, 104, 106} CM began before initial treatment in two studies^{103, 106} and after treatment in two studies.^{14, 104} The other two studies included trials that enrolled patients at different stages in the course of their illness and focused more generally on addressing patients’ care needs related to cancer.^{102, 105}

The *settings* for CM interventions included managed care organizations,^{102, 106} VAMCs,¹⁰² community hospitals and clinics,^{14, 103} home care organizations,^{102, 105} and cancer care centers.¹⁰⁴ Six studies were conducted in the United States and one in the United Kingdom.¹⁰⁴

Key Points

- CM is effective in improving selected cancer-related symptoms and functioning (physical, psychosocial, and emotional) but not overall QOL or survival (strength of evidence: low).
- CM improves patient satisfaction with care (strength of evidence: moderate).
- CM is effective in increasing the receipt of appropriate (i.e., guideline-recommended) cancer treatment (strength of evidence: moderate).
- CM does not significantly increase or decrease overall health care utilization or cost among cancer patients (strength of evidence: low).
- CM is more effective when targeted to cancer patients with lower levels of social support (strength of evidence: low).
- Greater intervention intensity and duration, integration of CM with patients’ usual care providers, and greater structuring of interventions through preintervention training and care protocols enhance the effectiveness of CM (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Quality of Life/Health Outcomes

Overall QOL and survival were generally not improved by CM in any of the studies that examined those outcomes interventions.^{14, 104, 105} CM was effective, however, in improving outcomes that were directly targeted by the intervention. For instance, using an intervention intended to help women recover after breast cancer surgery, Goodwin, et al. found that CM was effective in restoring normal ipsilateral arm function compared with usual care (93 percent vs. 84

percent).¹⁰³ Similarly, two studies in which case managers provided symptom management and psychosocial support for patients with lung cancer demonstrated improvements in symptoms and psychosocial or emotional functioning.^{104, 105} It should be noted, however, that in one of these studies, significant improvements were found in only three of 36 prespecified outcome measures,¹⁰⁴ raising the possibility that the improvements resulted by chance rather than as a result of CM. Another study found no differences in symptoms or functional outcomes with CM.¹⁴ In one study, patients receiving CM had declining perceived health status over the course of the study, while control patients' perceived health status steadily improved,¹⁰⁵ even in the presence of greater symptom distress and worse functioning. This seemingly contradictory finding may have indicated, as suggested by the authors, that education and monitoring by case managers instilled more realistic evaluations of health status among homebound patients with lung cancer.¹⁰⁵

Patient Satisfaction

Of four studies that analyzed various aspects of patient experience with the care they received,^{14, 102-104} three found CM to be superior to usual care. Two studies found that CM increased patients' (and caregivers') satisfaction with care.^{102, 104} Another CM intervention improved breast cancer patients' sense of having a choice in their treatment.^{103, 320} The fourth study showed no difference in perceived unmet needs¹⁴ among patients receiving CM compared with controls. A study examining the effect of CM on patients who had died found that CM increased the proportion of cancer patients dying at home rather than in an institution.¹⁰⁴ Whether or not home deaths reflected patients' and families' preferences were not reported.

Quality of Care Outcomes

Three studies examined the effect of CM on the use of health care services considered to represent high-quality care.¹⁰²⁻¹⁰⁴ All three found that CM improved the use of recommended services. An intervention specifically targeting the use of advanced directives succeeded in increasing the number of completed advanced directives.¹⁰² Other studies demonstrated increased use of breast-conserving surgery (with lymph node dissection and radiation treatment) for women with early-stage breast cancer¹⁰³ and the early use of radiation as adjunctive therapy for lung cancer.¹⁰⁴

Resource Utilization Outcomes

Five studies examined the impact of CM on resource utilization—including hospitalizations, ED visits, medical visits, and testing—and overall cost of care^{14, 102, 104-106} and found no reduction in overall cost of care. One study found that CM reduced the number of radiographic studies patients underwent but did not affect referrals, hospitalization rates, or the overall cost of care.¹⁰⁴ Other studies similarly demonstrated no difference between CM and controls in utilization of services.^{14, 102, 105, 106} In general, the estimated cost of the CM interventions was small. Thus, the cost of implementing CM had a minimal impact on the overall cost of care, which was driven mainly by the cost of hospitalizations.

Table 14. Characteristics and outcomes of studies of case management for patients with cancer

Author Year Quality	Cancer Type(s)	Patient Population	Setting	Sample Size	Outcomes			
					Health Outcomes	Patient Experience	Quality of Care	Resource Utilization, Cost
Engelhardt, et al. 2006 Fair	Multiple ^a	Any patient with cancer, or COPD or CHF with recent hospitalizations	3 VAMCs, 2 MCOs, home care organization (U.S.)	275	NR	↑ Satisfaction	↑ Advanced directive completion	=
Mor, et al. 1995 Fair	Multiple	Patients starting chemotherapy	2 hospital-based clinics, 8 private oncology practices (U.S.)	217	=	=	NR	=
Goodwin, et al. 2003 Fair	Breast	Women ≥ 65 with newly diagnosed cancer	13 community hospitals, 2 public hospitals (U.S.)	335	↑ Arm function after surgery	↑ Satisfaction	↑ Breast-conserving surgery with radiation therapy	NR
Ritz, et al. 2000 Poor	Breast	Women ≥ 21 with newly diagnosed cancer	Integrated health care system (U.S.)	210	↑ Less uncertainty about illness	NR	NR	=
Moore, et al. 2002 Fair	Lung	Patients completing initial cancer treatment	Cancer hospital, 3 outpatient cancer centers (UK)	203	↑ Improved symptoms, emotional functioning	↑ Satisfaction	↑ Radiation therapy	↑ Fewer x-rays
McCorkle, et al. 1989 Poor	Lung	Homebound patients	Home care program (U.S.)	166	↑ Improved symptoms, functional status ↓ Perceived health	NR	NR	=

Abbreviations: CHF, congestive heart failure; COPD; chronic obstructive pulmonary disease; MCO, managed care organization; NR, Not reported; UK, United Kingdom; U.S., United States; VAMC, Veterans Affairs Medical Center.

↑ Better with case management; = No difference; ↓ Worse with case management.

^a Studies may have examined multiple outcomes within an outcome category.

Effectiveness of Case Management by Patient Characteristics

CM is a high-intensity intervention that is most often deployed for patients with complex care needs. While cancer and its treatment may in and of themselves create complex care needs, it is possible that the utility of CM is greatest among high-risk or vulnerable patient subgroups. In our review, only one study explicitly targeted a high-risk group (homebound patients with lung cancer); this study did not show a stronger effect of CM than other studies.¹⁰⁵ Three studies evaluated whether measures of vulnerability or level of care needs predicted the success of CM within their study samples. In one study, patients were stratified into three groups based on a statistical model of predicted unmet needs.¹⁴ This study found no differences in any outcomes for any subgroups. Two other studies, however, both using CM for women undergoing treatment for breast cancer, found that CM was primarily effective in women with lower levels of social support, as indicated by being unmarried or living alone.^{103, 106} CM was most effective in this population of women in terms of ensuring use of appropriate services¹⁰³ and improving QOL.¹⁰⁶

Effectiveness of Case Management by Intervention Characteristics

No studies included head-to-head comparisons of different models of CM. One study compared a specialized home care CM program for cancer patients to a standard home care program delivered by a multidisciplinary team.¹⁰⁵ In that study of homebound lung cancer patients, both home care programs produced similar outcomes in terms of symptoms, functional status, and hospitalization rates. However, the study was poor quality and did not clearly specify the differences in activities and functions performed by the different home care models.

The CM interventions described in the included studies varied widely in their implementation. We analyzed this variation in an attempt to discern the features of successful compared with unsuccessful CM interventions. Heterogeneity in the outcome measures used across studies precluded a quantitative analytic approach (e.g., meta-regression). Our findings therefore derived from a qualitative synthesis of the six included studies.

Two studies reported on interventions that demonstrated significant improvements in multiple outcomes, including health outcomes, patient experience, and quality and utilization of care.^{103, 104} Another intervention was successful in achieving more focused improvements in targeted outcomes, including patient satisfaction and advanced directive completion.¹⁰² A visual scan of Table 8 reveals several features that, while not unique to these successful interventions, in the aggregate appear to distinguish them from others. Specifically, the interventions reported by Goodwin, et al. and Moore, et al. represented more intensive forms of CM, in that they included more contacts and were sustained over a longer period of time than most others. They also explicitly included integration between the case managers and the patients' usual care providers. Finally, those interventions, as well as the one reported by Engelhardt, et al. appeared to be more structured, as indicated by explicit descriptions of preintervention training for case managers and the use of care protocols to guide CM activities.

Aside from CM intensity, integration with primary care, and structure, we found no discernible pattern indicating that other aspects of CM – including modes of contact or principal CM functions – influenced effectiveness. It should be noted, however, that the specificity with which authors described the core functions performed by case managers was variable, which limited our ability to evaluate whether specific core functions influenced CM effectiveness. Likewise, no studies provided information on the average caseload of case managers at any given time, and only one explicitly reported the degree to which case managers received

supervision from a physician. Most case managers were nurses and most had flexibility for individualizing care plans, limiting our ability to comment on the value of these intervention components.

Consistency with Previous Systematic Reviews

A recent systematic review of CM to optimize cancer care pathways using a CM definition and study inclusion criteria similar but not identical to ours summarized seven studies, six of which were included in our review.¹⁰⁷ We excluded one study that was included in that review because it was a short-term intervention (4 weeks) intended to manage patients in the postoperative period after cancer surgery and did not meet our criteria for CM as a longitudinal intervention.¹⁰⁸ It should be noted that in that study, the authors reported a survival advantage among patients receiving CM.¹⁰⁸ Because of the potential importance of that finding, we reviewed the study in detail. There are several factors that limited our confidence in the finding of improved survival in that study. First, although reported as the primary outcome, a review of the initial study proposal revealed that survival was not an *a priori* outcome for the study. Second, the finding was based on a post-hoc, subgroup analysis. Third, the mechanism of improved survival suggested by the investigators was the psychosocial support provided by the intervention, but there were no differences between groups in psychosocial outcomes. Finally, the temporal relationship between the intervention and the observed differences in mortality, which did not accrue in the first 3 months after the 4-week intervention but rather were observed only after 2 years, was inconsistent with a causal association.

The authors of the prior systematic review concluded that the heterogeneity of CM studies made it impossible to comment on the effectiveness of CM in cancer care.¹⁰⁷ They also concluded that the poor specification around CM implementation (i.e., the “black box” nature of CM studies) precluded an analysis of effective elements of CM. We agree that the nature and quality of the literature demanded that any judgments about the effectiveness of CM for cancer patients, or the elements that make CM successful, be made cautiously. However, our analysis suggests that some conclusions can be made (as itemized in the Key Points section above).

Case Management for Patients with Serious Chronic Infections

Human immunodeficiency virus (HIV) and mycobacterium tuberculosis (TB) are serious infectious agents that, when inadequately treated, can be fatal. Both require treatment with multiple drugs and for long durations of time. For HIV, treatment must be continued indefinitely. Both are infectious, and treatment can reduce the chance of transmitting the infection to others. Thus, effective treatment of these infections is a clinical and public health priority. Treatment requires engagement by the infected person and adherence to regimens that are complex and can be associated with unpleasant side effects. Problems such as low health literacy, unstable living situations, and substance abuse can be important barriers to carrying out treatment plans. For both of these infections, a variety of public health programs have been tried to improve medication adherence and thereby to enhance clinical outcomes.

Description of Studies

Studies of Case Management for People with HIV

We identified five randomized controlled trials (RCTs) and three observational studies of CM programs for people infected with HIV (see Appendix N). Of the five RCTs, two were rated fair quality^{109, 110} and three were rated poor¹¹¹⁻¹¹³ (see Appendix G). Four of the trials were conducted in the United States and one in Canada.¹¹¹ The earliest included study was published in 1992 and the most recent in 2007.

Sample sizes ranged from 57 to 250 participants (total n = 736). Of the three observational studies, one was rated good quality,¹¹⁴ and two were rated poor.^{115, 116} All three observational studies were conducted in the United States and included a relatively small number of participants (sample sizes of 51, 280, and 588). The studies were published between 2001 and 2007.

All eight of these studies targeted low income populations except for one observational study restricted to women,¹¹⁵ the majority of participants in each study were male (54 to 93 percent). In two of the studies the majority (70 percent or more) of participants were Caucasian.^{111, 113} In the other six studies, 49 to 90 percent of participants were African American or Latino. The average age of study participants was 35- 45 years. One study targeted homeless and marginally housed individuals;¹¹⁴ three studies specifically included current intravenous drug use or other substance abuse as study eligibility criteria.^{109, 112, 115}

Studies of Case Management for People with Tuberculosis (TB)

We identified two RCTs (see Appendix N), both of which were rated fair quality (see Appendix G). One was conducted in the United States and published in 2006;¹¹⁷ one was conducted in Taiwan and published in 2007.¹¹⁰ Sample sizes, respectively, were 520 and 114 (3 study arms). We also identified two observational studies; one was rated good quality,¹¹⁸ and one was rated poor.¹¹⁹ Both studies utilized a retrospective cohort design and were of similar sample size (n=343 and n=369). One was conducted in the United States and published in 2002;¹¹⁸ one was conducted in Taiwan and published in 2006.¹¹⁹ One of the trials restricted enrollment to individuals with latent tuberculosis infection (LTBI).¹¹⁷ The other three studies examined programs serving patients with active TB infection. The majority of participants in both U.S. studies were nonwhite and male; in one of the U.S. studies, more than 30 percent were substance abusers and more than 40 percent had concurrent infection with HIV; eligibility for the other U.S. study included spending the previous night in a homeless shelter. Participants in the Taiwan studies were mostly male with a mean age range of 53 to 68; socioeconomic status was not reported.

Approach to Case Management for Chronic Infections

CM *interventions* in all of the studies focused on linking individuals to needed services, including medical, mental health, social, and drug treatment services (see Table 15). The programs generally included counseling and education components. The TB programs tended to have a greater emphasis on the coordination and monitoring of medications. In one of the HIV programs,¹¹³ the participants were housebound patients with AIDS, and the case managers had caseloads of only 12 or less. Mode of case manager/client contact (reported in three studies) was either strictly face-to face or in combination with telephone contact. The disciplines of the case

managers were usually nurses or counselors. The length of the interventions was 6 months in all of the TB studies and 6-12 months in the HIV studies.

While one of the trials was a head-to-head comparison of less intensive to more intensive CM for TB treatment,¹²⁰ the rest of the studies used a usual care comparison group. The control groups generally had access to all the same services as the intervention groups (community-based services, or usual clinic or in-home care), but acquired them through self-direction or without the assistance or involvement of a designated case manager.

Table 15. Characteristics of case management interventions for patients with HIV/AIDS or TB

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Caseload	Role of Usual Care Provider	Supervision by Physician	Profession	Pre- intervention Training	Use of Protocols or Scripts
Husbands 2007 Poor	6	NR	<ul style="list-style-type: none"> • Assessment • Self-management support • Coordination 	NR	NR	Not integrated	No	NR	Yes	No
McCoy 1992 Poor	12	Unclear	<ul style="list-style-type: none"> • Assessment • Education • Coordination 	NR	30 - 35	Not integrated	No	BS health educators, no social work training	Yes	No
Nickel 1996 Poor	30	In-home care	<ul style="list-style-type: none"> • Assessment • Planning • Coordination • Monitoring 	Weekly phone, monthly visit while receiving in-home care	NR	Integrated	Yes	Nurses specialized in HIV care	NR	No
Sorenson 2003 Fair	12	Phone, in-person contact	<ul style="list-style-type: none"> • Education • Self-management support • Coordination 	44 contacts per year	20	Not integrated	Yes	Para-professionals certified as chemical dependency counselors	Yes	No
Wohl 2006 (Sanson 2008) Fair	6	In clinic	<ul style="list-style-type: none"> • Assessment • Self-management support • Coordination 	14 weekly contacts	NR	Integrated	NR	"Trained case manager"	NR	No
Nyamathi 2006 Fair	6	In-person	<ul style="list-style-type: none"> • Education • Self-management support • Coordination 	1-hour weekly	NR	Integrated	Yes	Nurse	Yes	No
Hsieh 2007 Fair	6	Clinic and home visits	<ul style="list-style-type: none"> • Education • Coordination • Monitoring 	Group 1: DOT daily for 2 months; weekly home visits for 6 months; Group 2: monthly home visit for 6 months	NR	Integrated	Yes	NR	NR	No

Abbreviations: BS, bachelor of science; CM, case management; DOT, direct observed therapy; NP, nurse practitioner; NR, not reported; RN, registered nurse; SW, social worker.

The patient-centered *outcomes* included in these studies (see Table 16) often were measures of response to antibiotic treatment. All of the TB studies used measures of successful suppression of the infection. Two of the HIV studies^{110, 114} included viral load or CD4 count as outcome measures. Other patient-centered outcomes included measures of mental health, QOL, and risk behaviors. Quality of care outcomes included medication adherence rates and receipt of community services. Resource utilization measures included outpatient and ED utilization, hospitalization rates, and overall program costs.

The *settings* for these CM programs included HIV/AIDS service organizations,^{111, 112} public health clinics,^{110, 118} public hospitals,^{109, 119, 120} and homeless shelters.¹¹⁷ All of these studies were conducted in large metropolitan areas.

Key Points

- CM does not improve survival among patients with HIV infection (strength of evidence: low).
- Short-term CM management programs that emphasize medication adherence improve rates of successful treatment for TB in vulnerable populations (strength of evidence: low).
- Evidence is insufficient to determine whether CM improves antiviral treatment of HIV infection.
- More frequent visits by a case manager are associated with higher rates of clinical improvement in HIV and TB infections (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Two clinical trials of HIV patients included survival as a primary outcome. A fair-quality trial¹⁰⁹ reported 16 percent mortality at 18 months, and a poor-quality clinical trial of patient with AIDS reported 50 percent mortality at 6 months. Neither study found a significant difference in mortality between the CM and control groups.

The studies of populations with TB had CM programs in which the case manager emphasized adherence to drug treatment regimens, and these programs generally found higher rates of successful treatment with CM. The study with the best methodological quality was a good quality interrupted time-series evaluation.¹¹⁸ Using a measure of achieving adequate treatment, a successful outcome was achieved for 69 percent of patients during the time period in which conventional directly observed therapy (DOT) was used. This rate increased to 81 percent 86 percent in successive time periods in which CM was added to DOT. These rates stayed consistent over four successive 6-month time periods, suggesting that this finding was not due to a time trend unrelated to the use of CM. Higher rates of treatment completion with CM were also observed in two fair-quality clinical trials of patients with TB.^{117, 120} A poor-quality observational study compared a population of TB patients receiving CM to a population in a different health system. Treatment success was 87 percent in the CM group and 73 percent in the comparison group. We found no other studies of CM for TB, but we cannot exclude publication bias.

In a fair-quality clinical trial, HIV patients were randomized to CM, directly observed antiretroviral administration, or usual care.¹¹⁰ Viral load dropped in all three groups, without significant differences among the programs. In a good-quality cohort study, the quantity of CM

was used as a predictor variable in a multivariate analysis.¹¹⁴ The quantity of CM had a moderate association with rise in the CD4 count but was not associated with drops in viral load.

Some clinical trials in HIV populations also measured psychological distress^{109, 111} and quality of well-being (QWB).¹¹³ Changes in these measures showed little difference between the CM and control groups.

Quality of Care Outcomes

The quality measures have included medication adherence and (for HIV patients) behaviors associated with viral transmission. CM of moderately high intensity (weekly contacts by case manager) has not been shown to bring significant improvement in self-reported medication adherence for HIV.¹¹⁰ In a study of TB patients¹²⁰ medication adherence was only slightly higher in the CM groups. CM has not been demonstrated to improve viral transmission behaviors.

Resource Utilization Outcomes

Because the studies in this clinical category often include vulnerable and underserved populations, the CM programs focus on facilitating and increasing provider visits. However, CM generally had little effect on the rate of clinic visits. While CM was associated with increased clinic visits in a poor-quality observational study of HIV patients,¹¹⁵ the visit rates were not significantly changed in a fair-quality clinical trial¹²¹ and a good-quality observational study.¹¹⁴

In a fair-quality clinical trial of an HIV population, hospitalization rates were lower in the CM group than in the usual care group, but ED visits were not significantly different.¹²¹ However, in a good-quality observational study, CM was not associated with either ED or inpatient utilization.¹¹⁴ The study finding a reduction of hospitalizations also found lower overall health care costs in the CM group.¹²¹ A poor-quality clinical trial¹¹¹ also found lower (but not significant) overall costs in the CM group.

Table 16. Characteristics and outcomes of studies of case management for patients with HIV/AIDS or TB

					Outcomes			
Author Year Quality	Patient Population	Disease	Setting	Sample Size	Health Outcomes	Patient Experience	Quality of Care	Resource Utilization, Cost
Husbands 2007 Poor	HIV+, receiving services from AIDS service organization	HIV/AIDS	AIDS service organization	99	NR	= QOL, physical and mental health, social functioning, risk- behavior <i>Subgroup analyses: very depressed</i> ↑ Physical and mental health, social functioning, lower risk behaviors	NR	= Direct cost health and social services
McCoy 1992 Poor	Low income, HIV+, IV drug users	HIV+	County public health AIDS program	40	NR	NR	NR	NR
Nickel 1996 Poor	AIDS patients referred to home care	AIDS	Home health care	57	NR	= QOL	NR	NR
Sorenson 2003 Fair	HIV+, substance abusers	HIV/AIDS	Hospital	190	NR	= Substance use, physical and psychological status, quality of living situation ↑ Lower risk behaviors	= Treatment services received	
Wohl 2006; Sanson 2008 Fair	HIV+, receiving care through public health HIV clinics	HIV/AIDS	Public health clinic	250	= Viral load, CD4+ cell, opportunistic infection	NR	= Medication adherence	↑ Hospital days = ED visits ↑ Net program cost
Nyamathi 2006 Fair	Homeless, with latent TB infection	Latent TB	Healthcare clinic serving low-income	520	NR	NR	↑ Adherence to treatment, TB knowledge	NR
Hsieh 2007 Fair	Individuals with TB infection (Taiwan)	TB	Hospital-to- community	114	↑ Sputum conversion, chest x-ray improvement, treatment success	NR	↑ Adherence to medication and. treatment completion	NR

Abbreviations: CM, case management; HIV, human immunodeficiency virus; IV, intravenous; ED, emergency department; NR, not reported; OP, outpatient; QOL, quality of life; TB, tuberculosis.

↑ Better with case management; = No difference; ↓ Worse with case management.

Effectiveness of Case Management by Patient Characteristics

Because all of the studies in this clinical category had relatively small sample sizes, there were few sub-group analyses. The influence of CM on patient outcomes applies only to the limited populations that were studied. As previously stated, this group of studies included mostly underserved and impoverished populations.

Effectiveness of Case Management by Intervention Characteristics

One fair-quality clinical trial for TB patients had a head-to-head comparison of two levels of intensity of CM (weekly home visits vs. monthly home visits).¹²⁰ The sample size was small (32 participants per study arm). The measure of treatment success was significantly higher in the group that received weekly visits. A good-quality observational study of HIV patients¹¹⁴ measured intensity of CM by frequency of contact with case managers). However, the highest-frequency category could still be less often than monthly. The intensity of CM was evaluated for a large number of possible outcomes. The only outcome that showed a positive association with CM intensity was improvement in CD4 count.

Case Management for Other Clinical Conditions

CM can be adapted to a wide variety of community settings and clinical problems. While the clinical categories described earlier in this report captured most of the studies of CM, there were seven additional studies that do not fall into those categories. These additional studies related to two care coordination themes. The first is coordinating services for low income individuals who often have serious problems with access to clinical services. The second theme is patient education and coordination of services following hospital discharge for acutely disabling medical conditions (stroke and renal failure requiring dialysis). In general, these studies had findings that were consistent with the results described earlier in this report.

Description of Studies

We identified five randomized controlled trials of CM programs for clinical populations different from those already described in this report (see Appendix O). Two of the trials were good quality, one was fair quality, and two were rated poor (see Appendix G). Four were conducted in the United States,¹⁷⁻²⁰ and the remaining trial was conducted in Hong Kong.²¹ These trials were published between 2002 and 2010. In addition to these five randomized controlled trials, there are two observational studies of CM that have not been previously covered in this report.^{122, 123} Both of the observational studies were rated as having poor quality methods and were published since 2007. Four of the studies (two trials and two observational studies) examined low income populations, although the nature of the CM programs was quite variable across these four studies. The other three clinical trials examined patients undergoing home peritoneal dialysis or patients undergoing rehabilitation after a stroke.

A good-quality clinical trial evaluated a CM program for patients followed in primary care clinics operated by a county health department in California.¹²⁴⁻¹²⁶ Patients were eligible for the study if they had diabetes mellitus, coronary artery disease, peripheral vascular disease, cerebrovascular disease, hypertension, or elevated cholesterol and/or triglyceride levels. Of the 419 participants, mean age was 56 years, 65 percent were female, 63 percent were Hispanic, and 38 percent were employed. Sixty-three percent had type 2 diabetes. In the intervention group,

CM was performed by a team consisting of a registered nurse and a dietician. The case managers used protocols that focused on lifestyle modifications, and the intervention lasted 15 months. The control group received the usual model of primary care provided in the four participating clinics. The primary outcome was a measure of risk factors for atherosclerosis (the Framingham risk score).

The second clinical trial that focused on a low income population examined homeless patients who were recruited at the time of an acute hospitalization in the United States.¹²⁷ The participants had a wide variety of chronic medical conditions. The intervention included CM for up to 18 months, and the intervention group patients also were provided placement in stable housing. The control group received no specific services following hospital discharge, but there were other CM services available in the community. The outcomes were counts of hospitalizations and ED visits. This study design makes it difficult to discern the unique effects of CM, in that there was an important cointervention (placement in permanent housing) that was not available to the control group.

Two poor-quality observational studies conducted in the United States evaluated CM programs for low-income people. The first evaluated 492 uninsured adults, 70 percent of whom were female (mean age 35 years).¹²³ CM was provided by a team consisting of a registered nurse and social worker. There was no comparison group, and the primary outcome was ED visit rates (measured 6 months prior to starting CM and 6 months after completing CM). Mean duration of CM was 179 days. The second observational study evaluated 159 patients who received services from a CM program designed for low-income patients with epilepsy.¹²² Mean age was 41 years, and 58 percent were male. Two-thirds were uninsured, 59 percent were unemployed, and none had yearly incomes greater than \$5,000. Self-reported estimates of seizure control and ED visits were assessed by a questionnaire administered after completing the CM program.

A fair-quality clinical trial conducted in Hong Kong evaluated a 6-week CM program for patients who perform home peritoneal dialysis.¹²⁸ The 85 study participants were recruited during an acute hospitalization. The outcome data were derived from patient questionnaires administered at 6 and 12 weeks after hospital discharge.

Two poor-quality clinical trials evaluated CM programs for patients who had recently undergone acute rehabilitation following a stroke. A small randomized trial evaluated utilization outcomes of 28 stroke patients who were being discharged from an inpatient rehabilitation service in New York.¹²⁹ The case managers were social workers, and the program focused on ameliorating barriers to ongoing rehabilitation. Control group patients received usual care, without the services of the social workers. The outcomes were measures of utilization over three months. The second trial also enrolled patients (n=96) who were being discharged from an inpatient stroke unit. The case managers were advanced practice nurses. The CM focused on coordination between neurology consultants and the primary care physicians. Patients in the control group did not receive these coordination services. The outcome measures included functional status, QOL, and measures of stroke-related quality of medical care (all measured at three months after hospital discharge).

Key Points

- CM programs that focus on cardiac risk factor improvement result in small improvements in risk these factors (strength of evidence: low).
- CM programs for patients who recently have had a stroke improve quality of life (insufficient evidence).
- CM programs that serve homeless or uninsured patients reduce ED visits (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

In general the studies included in this category had short durations of followup. They also included diverse populations and used a variety of outcome measures. Of the two good-quality clinical trials, only one measured patient centered outcomes: a variety of cardiac risk factors that were measured in the trial of CM for low income adults enrolled in primary care clinics.^{124, 125} In this trial the mean Framingham risk score was one-point lower in the intervention group at 15 months. The major contributor to the difference between groups was better achievement of blood pressure goals in the intervention group.

The two clinical trials of patients with recent strokes had poor methodological quality, and only one¹³⁰ measured patient centered outcomes. This study had a small sample size and used multiple outcome measures, suggesting that some changes may have been due to chance. The study found small improvements in quality of life in the CM group but no differences in functional status or blood pressure control.¹³⁰

Studies in two other clinical settings also found improvements in patient centered outcomes with CM. In the trial of CM for patients undergoing home peritoneal dialysis, patients in the CM group had small improvements in several measures of functioning and satisfaction, compared with patients in the control group.¹²⁸ The observational study of patients with seizures found a reduction in self-reported seizure rates.¹²² However, there was no comparison group in this study, and it is possible that part of this change was due to regression to the mean.

Resource Utilization Outcomes

Many of the studies in this category reported on utilization of healthcare services, with ED visits being the most commonly measured type of utilization. One of the good-quality trials had ED visits as a primary outcome.¹²⁷ Compared with the usual care group, the homeless CM patients had, on average, about one fewer ED visit per year, but this group also received housing assistance in addition to CM. Three other studies that were rated as poor quality^{122, 123, 129} also found lower ED visit rates in patient groups who received CM.

The good-quality trial of CM for homeless people¹²⁷ also examined hospitalization rates as a utilization outcome. While these rates did not differ significantly between the CM and control groups, patients in the CM group had about three fewer hospital days per year. However, this difference in length of hospital stays may be due to the housing assistance provided as a cointervention to the CM group.

Effectiveness of Case Management by Patient Characteristics

Although four of the studies in this category addressed CM for low income individuals, the populations were quite diverse, ranging from homeless people to patients who were followed

regularly in safety net clinics. The outcome measures in these studies were diverse, and the only outcome that was measured in multiple studies was ED visits. This measure improved in all the studies, so there do not appear to be particular patient characteristics that influence this utilization outcome. The other outcomes in these studies are different enough that it is not possible to draw conclusions based on patient subgroups.

Effectiveness of Case Management by Intervention Characteristics

The studies in this category tended to examine CM programs that were tailored to the patient populations (ie, cardiac risk factor reduction, management of home dialysis, coordination of care for the uninsured), and the outcomes were specific to each type of program. The main difference that can be examined is length of CM. In the four studies of low income people,^{122-124, 127} the CM was continued for 6 to 18 months. In the three other studies (of home dialysis and stroke), the CM lasted 3 months or less. Nevertheless, there were no clear trends in outcomes based on CM duration within these ranges.

Summary and Discussion

Case management (CM) is a strategy for improving the delivery of clinical services to patients with complex needs. The types of patient who potentially could benefit from case management fall into four distinct categories:

- Patients who have serious chronic diseases that are progressive and life-threatening but can be improved with proper treatment, such as congestive heart failure (CHF) or HIV infection.
- Patients with progressive debilitating and often irreversible diseases for which supportive care can enhance independence and quality of life, such as dementia or multiple chronic disease in the aged.
- Patients who have progressive chronic diseases for which self-management can improve health and functioning, such as diabetes mellitus.
- Patients for whom serious social problems impair their ability to manage disease, such as the homeless.

For all of these clinical categories health care resources generally are available but may be inaccessible or poorly coordinated. Case managers can help to surmount these problems, but the role of the case manager is complex. Depending on the organization and strategy of CM programs, the case manager can play distinctly different roles:

- A care provider who helps patients improve their self-management skills and/or helps caregivers to be more effective in helping and supporting patients.
- A collaborative member of the care delivery team who promotes better communication with providers and advocates for implementation of care plans.
- A patient advocate who evaluates patient needs and works to surmount problems with access to clinical services.

There are multiple strategies for fulfilling these roles, and CM programs are consequently complex and often difficult to replicate. Organizationally, programs can be free-standing or imbedded in clinical settings (usually primary care or specialty practices). Case managers can interact with patients in their homes, in clinics, or by telephone. Case managers can have caseloads of hundreds or only a few dozen. Case managers can follow prespecified protocols or can develop personalized care plans based on patient assessments. Case managers can work independently or can function as a member of a CM team. The studies of CM use a variety of approaches to describe their programs, and full specification of the program's content often is not possible. Acknowledging this heterogeneity of study populations, interventions, and outcomes, we sought to discern the conditions under which CM was effective or ineffective.

Limitations of this Review

The multiplicity of roles and variability of day to day activities means that evaluations of CM can never fully specify the content of the intervention. Furthermore, few organization have the potential scope (in terms of patient base and clinical resources) to conduct evaluations that directly compare different CM approaches. Thus, nearly all evaluations have compared a customized CM program to a "usual care" model in which patients receive no CM services.

Synthesizing the evidence about CM requires indirect comparisons among different types of clinical programs.

Despite these extensive methodological challenges, the evidence base about CM is impressive. More than 50 randomized controlled trials have been conducted in a variety of patient populations, and a smaller number of good-quality quasi-experimental studies also have been reported. The total number of participants in these studies approaches 100,000. The majority of these studies have given good descriptions of the patient populations, making it possible to organize the evidence by population groupings (as was done in this report). In some cases, there has been enough similarity in patient populations that indirect comparisons of different types of programs can be made with moderate confidence.

Most of the individual clinical trials of CM have had modest sample sizes (less than 500 participants per intervention arm). This size limitation has been a barrier to the analysis of patient sub-groups, and many of the trials have not reported results by sub-group. As a result, analyses of sub-group results mostly are based on indirect comparisons.

Another important limitation of our review is that we examined only studies of CM, and in most cases the CM program was compared with “usual care,” not to other interventions. Some of the outcomes achieved by CM may have been achievable using less intensive, more focused interventions. CM typically involves nurses, or other health professionals, performing multiple functions to comprehensively meet patients’ needs, and the evidence suggests that CM is most effective when it involves prolonged and intense engagement with patients. Our review did not address whether the outcomes achieved by successful CM interventions could have been achieved with more narrowly tailored interventions, targeting the specific deficits in care most likely to cause poor outcomes. For instance, brief transitional care interventions may be as effective as more comprehensive CM in reducing readmission among hospitalized patients. Comparing intensive and comprehensive CM interventions to more focused interventions would provide guidance as to when investments in CM are most warranted.

Conclusions

The main findings of this review are summarized in Table 17, below, and Appendix P summarizes the strength of the evidence. The cumulative evidence about case management (CM) is sufficient to draw several conclusions, some of which pertain to the inability of CM programs (as they have been commonly deployed) to achieve some desired outcomes. Generally, the conclusions reached in this report pertain only to specific patient populations. Because CM programs generally are customized to the patient groups served, it usually is not possible to apply the results to other patient populations. In this review, we found that, on balance, CM had limited impact on patient-centered outcomes, quality of care, and resource utilization among patients with chronic medical illness. The most positive findings are that CM improves the quality of care, particularly for patients with serious illnesses that require complex treatments (cancer and HIV). For a variety of medical conditions, CM improves medication adherence and self-management skills. CM also improves quality of life in some populations (congestive heart failure [CHF] and cancer) and tends to improve satisfaction with care. For the caregivers of patients with dementia, targeted CM programs improve levels of stress, burden, and depression.

We found low-level evidence that CM is effective in improving resource utilization (particularly lower hospitalization rates) only for patients with CHF or those with chronic homelessness. In most other cases, CM programs have not demonstrated cost savings. For patients who receive CM for multiple chronic diseases, there is high-level evidence that the programs do not reduce Medicare expenditures. However, the impact of CM appeared to be greatest when it was targeted towards patients with the highest previous levels of health care utilization. The implication of this finding is that those with the greatest need for assistance with clinical management and care coordination, patients with low levels of social support, and/or patients at highest risk for poor outcomes might be more likely to benefit from CM. CM may be best suited for only the highest risk patients, who are most likely to benefit from high intensity engagement that addresses a wide variety of needs. It may have more limited impact for patients with more focused (less complex) care needs. While the effectiveness of CM may depend on selection of the appropriate target population, the published studies suggest that this type of careful case selection is difficult to implement.

The results of trials across different clinical conditions suggest that CM effectiveness was greater when the intervention was more prolonged, included more patient contact, and included face-to-face (rather than telephone only) interactions. This finding validates the premise that the relationship between case manager and patient is likely to be a key ingredient for successful CM interventions. CM also appears to be most effective when the case manager works closely with patients' usual care providers (usually primary care physicians) and/or collaborates with a physician (or multidisciplinary team of health care providers) with expertise in managing the targeted medical condition. This finding suggests that CM may be most effective when case managers are embedded within a collaborative, team-based intervention model. Finally, there also is some evidence that CM is successful in achieving outcomes when the intervention includes specific training modules and protocols that are tailored towards those outcomes. This suggests that the breadth and flexibility of CM may need to be complemented by focused efforts – including specific training, guidelines, and protocols – to achieve explicitly targeted outcomes.

Table 17. Summary evidence table: Comparative effectiveness of case management for adults with medical illness and complex care needs

Key Question	Condition/ Disease	Strength of Evidence	Conclusion
Key Question 1a: In adults with chronic medical illness and complex care needs, is case management effective in improving <i>patient-centered outcomes</i> , including mortality, quality of life, disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care?	Multiple chronic diseases in older adults	High	<i>Mortality.</i> CM programs that serve patients with multiple chronic diseases do not reduce overall mortality.
		High	<i>Functional status.</i> CM programs that serve patients with multiple chronic diseases do not result in clinically important improvements in functional status.
	Frail elderly	Low	<i>Mortality.</i> CM does not affect mortality in frail elders.
	Dementia	Moderate	<i>Depression and strain.</i> CM programs that serve patients with dementia reduce depression and strain among caregivers.
		Moderate	<i>Time to nursing home placement.</i> CM programs that serve patients with dementia and have duration of no longer than two years do not confer clinically important delays in time to nursing home placement.
	Diabetes	Moderate	<i>Glucose management.</i> CM programs that serve diabetic adults do not improve glucose management.
		Moderate	<i>Lipids, blood pressure, BMI/weight.</i> CM programs that serve diabetic adults do not improve measures of lipid management, blood pressure management, or BMI/weight.
		Low	<i>Mortality.</i> CM programs that serve adults with diabetes do not reduce mortality.
		Low	<i>Quality of life.</i> CM programs that serve diabetic adults do not improve quality of life.
	Cancer	Moderate	<i>Satisfaction with care.</i> CM programs that serve patients with cancer improve satisfaction with care.
		Low	<i>Cancer-related symptoms, functioning, quality of life, survival.</i> CM improves selected cancer-related symptoms and functioning (physical, psychosocial, and emotional) but not overall quality of life or survival.

Key Question	Condition/ Disease	Strength of Evidence	Conclusion
	CHF	Moderate	<i>Patient satisfaction.</i> CM programs that serve patients with CHF increase patient satisfaction.
		Low	<i>Quality of life.</i> CM programs that serve patients with CHF improve CHF-related quality of life.
	HIV	Low	<i>Survival.</i> CM programs that serve adults with HIV infection do not improve survival.
	Other chronic conditions	Low	<i>Cardiac risk factors.</i> Case management programs that focus on cardiac risk factors result in small improvements in these risk factors
Key Question 1b: In adults with chronic medical illness and complex care needs, is case management effective in improving <i>quality of care</i> , as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior?	Multiple chronic diseases	Moderate	<i>Patient perception of care coordination.</i> CM programs that serve patients with multiple chronic diseases increase patients' perceptions of the coordination of their care.
	Dementia	Low	<i>Clinical guideline adherence.</i> CM programs that focus on clinical guideline measures for care of dementia increase adherence to those measures.
	Diabetes	Low	<i>Medication and screening adherence.</i> CM programs that serve diabetic adults improve medication adherence and adherence to recommended screening tests.
	Cancer	Moderate	<i>Appropriate treatment.</i> CM programs that serve patients with cancer increase the receipt of appropriate (i.e., guideline-recommended) cancer treatment.
	CHF	Moderate	<i>Self-management behaviors.</i> CM increases patients' adherence to self-management behaviors recommended for patients with CHF.
	TB	Moderate	<i>Treatment success.</i> Short-term CM programs that emphasize medication adherence improve rates of successful treatment for tuberculosis in vulnerable populations.
Key Question 1c: In adults with chronic medical illness and complex care needs, is case management effective in improving <i>resource</i>	Multiple chronic diseases	High	<i>Medicare expenditures.</i> CM programs that serve patients with multiple chronic diseases do not reduce Medicare expenditures.

Key Question	Condition/ Disease	Strength of Evidence	Conclusion
<i>utilization</i> , including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits)?		Moderate	<i>Hospitalization rates.</i> CM programs that serve patients with multiple chronic diseases do not reduce overall rates of hospitalization.
	Frail elderly	Low	<i>Hospitalization rates.</i> CM does not decrease acute hospitalizations in the frail elderly.
	Dementia	Moderate	<i>Health care expenditures.</i> CM does not reduce health care expenditures for patients with dementia.
		Moderate	<i>Physician visits.</i> CM does not reduce the use of physician visits for patients with dementia.
		Low	<i>Hospitalization rates.</i> CM does not increase acute care hospitalizations rates for patients with dementia.
	Diabetes	Low	<i>Resource utilization.</i> CM programs that serve diabetic adults do not improve resource utilization.
	Cancer	Low	<i>Health care utilization, cost of care.</i> CM programs that serve patients with cancer have little effect on overall health care utilization and cost of care.
	CHF	Low	<i>Hospital readmission rates.</i> CM reduces readmission rates among hospitalized CHF patients at high risk for readmission.
	Other clinical conditions	Low	<i>Emergency department visits.</i> Case management programs that serve homeless or uninsured patients reduce emergency department visits.
Key Question 2: Does the effectiveness of case management differ according to <i>patient characteristics</i> , including but not limited to: particular medical conditions, number or type of comorbidities, patient age and socioeconomic status, social support, and/or level of formally assessed health risk?	Multiple chronic diseases	Low	<i>Disease burden.</i> CM programs that serve patients with multiple chronic diseases are more effective for reducing hospitalization rates among patients with greater disease burden.
	Diabetes	Low	<i>Race, ethnicity, type of diabetes.</i> CM is not more effective at improving health outcomes among particular racial and ethnic sub-groups.

Key Question	Condition/ Disease	Strength of Evidence	Conclusion
	Cancer	Low	<i>Level of social support.</i> CM programs that serve patients with cancer are more effective when targeted to cancer patients with lower levels of social support.
Key Question 3: Does the effectiveness of case management differ according to <i>intervention characteristics</i> , including but not limited to: practice or health care system setting; case manager experience, training, or skills; case management intensity, duration, and integration with other care providers; and the specific functions performed by case managers?	Multiple chronic diseases	Moderate	<i>Personal contact.</i> CM programs that serve patients with multiple chronic diseases are more effective for preventing hospitalizations when case managers have greater personal contact with patients and physicians.
	Dementia	Low	<i>Duration.</i> CM programs that serve patients with dementia who have in-home spouse caregivers and continue services for longer than two years are more effective for delaying nursing home placement than programs providing services for 2 years or less.
	Cancer	Low	<i>Intensity, integration, training, protocols.</i> CM programs that serve patients with cancer are more effective when the CM is more intensive, better integrated with patients' usual care providers, and employs preintervention training and care protocols.
	CHF	Low	<i>Multidisciplinary team.</i> CM is more effective in improving outcomes among CHF patients when case managers are part of a multidisciplinary team of health care providers.
	TB and HIV	Low	<i>Visit frequency.</i> More frequent visits by a case manager are associated with higher rates of clinical improvement in HIV and TB infections.

Abbreviations: CM, case management; BMI, body mass index; CHF, congestive heart failure; HIV, human immunodeficiency virus; TB, tuberculosis.

Future Research

The existing evidence base includes a large number of randomized controlled trials comparing case management (CM) to “usual care.” In some cases (particularly the MCCD study)¹⁷ the studies had large sample sizes and good overall methodological quality. The results of such evaluations are relatively clear, and there is a relatively low yield in continuing to repeat such studies. Instead, future clinical research needs to address the gaps in the current evidence base. These gaps include:

- Lack of effective risk assessment tools for choosing candidates for CM. Some published trials²⁰ have used existing tools, but no studies have compared tools or rigorously examined patient subgroups to learn which patients achieve the greatest benefits from CM. The factors included in better risk profiles could include:
 - Demographics including age, gender, and ethnicity
 - Indicators of socioeconomic status and access to health care
 - Measures of social support
 - Health care utilization profiles
 - Clinical risk factors for adverse outcomes
- Lack of understanding of the length of time to continue CM. Nearly all trials have set seemingly arbitrary durations of the intervention (often 1-2 years). It is not known when the benefits of the intervention have been achieved. Some of the negative results may be due to the CM being too short. This is particularly important if developing an effective long-term relationship between the patient and case manager affects the program’s success.
- Imprecision about the intensity of CM. Existing trials have infrequently examined whether patient outcomes are influenced by the frequency of case manager contact, the length and content of the contacts, and the approach to followup of problems.

Other examples of CM elements that should be explicitly described in future research include:

- Training received by case managers
- Case manager experience
- Specific functions of case managers, and the distribution of effort devoted to different activities
- Modes of contact (clinic visits, home visits, telephone calls)
- Average caseload
- Relationship to other health care providers
- Use of protocols, guidelines, and information technology

CM typically involves case managers providing both direct clinical support and coordination for patients, as well as education and empowerment to enable patients to better manage their own conditions and coordinate their own care. Better specification of intervention components and population characteristics would contribute to greater understanding of when interventions should emphasize direct support compared with patient education.

Many CM interventions employed more than one case manager, but few studies examined the effectiveness of CM delivered by different case managers. CM is a human intervention, and the effectiveness of CM may vary substantially according to the skills, experience, and

personality of the person delivering the intervention. Understanding how much variability there is from one case manager to another would provide valuable information about the degree to which CM can be standardized, and the importance of choosing individuals to implement CM.

As discussed above, future research should compare CM to other interventions designed to achieve similar outcomes, particularly interventions that are less intensive or more narrowly focused and may thereby achieve desired outcomes more efficiently. Such studies would help determine in which situations CM adds value over potentially less costly interventions.

References

1. Institute of Medicine. Crossing the quality chasm: A new health system for the 21st century. Washington DC: The National Academies Press; 2001.
2. Wolff JL, Starfield B, Anderson G. Prevalence, Expenditures, and Complications of Multiple Chronic Conditions in the Elderly. *Arch Intern Med*. November 11, 2002 2002;162(20):2269-2276.
3. Bodenheimer TB-M, R. Care Management of Patients with Complex Health Care Needs The Synthesis Project: Princeton; 2009:1-36.
4. Boulton C, Green AF, Boulton LB, Pacala JT, Snyder C, Leff B. Successful models of comprehensive care for older adults with chronic conditions: evidence for the institute of medicine's "Retooling for an aging America" report. *Journal of the American Geriatrics Society*. Vol 57; 2009:2328-2337.
5. Kane RL. What Can Improve Chronic Disease Care? *Journal of the American Geriatrics Society*. 2009;57(12):2338-2345.
6. McDonald KM, et al. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies (Vol. 7: Care Coordination). In: Shojania KG MK, Wachter RM, Owens DK, editors, ed. Vol AHRQ Publication No. 04(07)-0051-7: Agency for Health Care Research and Quality: Rockville, MD; 2007.
7. Kersbergen AL. Case management: A rich history of coordinating care to control costs. *Nursing Outlook*. 1996;44(4):169-172.
8. Knollmueller R. Case management: what's in a name? *Nurs Manage*. 1989;20(10):38-42.
9. Shueman S. A model of case management for mental health services. *Q Rev Bull*. 1987;13:314-317.
10. Johnson P, Rubin A. Case management in mental health: a social work domain? *Social Work*. 1983;28:49-55.
11. Intagliata J. Improving the quality of of community care for the chronically mentally disabled: the role of case management. *Schizophr Bull*. 1982;8:655-674.
12. Lamb G. Conceptual and methodological issues in nurse case management research. *Adv Nurs Sci*. 1992;15(2):16-24.
13. Krumholz HM, Currie PM, Riegel B, et al. A taxonomy for disease management: a scientific statement from the American Heart Association Disease Management Taxonomy Writing Group. *Circulation*. Sep 26 2006;114(13):1432-1445.
14. Mor, Vincent, Wool, et al. The Impact of Short Term Case Management on Cancer Patients' Concrete Needs and Quality of Life. *Advances in Medical Sociology*. Issue. Vol 6; 1995:269-294.
15. AHRQ. Methods Reference Guide for Effectiveness and Comparative Effectiveness Reviews, Version 1.0. October 28, 2010 Draft posted Oct. 2007.
16. Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions--agency for healthcare research and quality and the effective health-care program. *J Clin Epidemiol*. May 2010;63(5):513-523.
17. Peikes D, Chen A, Schore J, Brown R. Effects of Care Coordination on Hospitalization, Quality of Care, and Health Care Expenditures Among Medicare Beneficiaries. *JAMA: The Journal of the American Medical Association*. February 11, 2009 2009;301(6):603-618.

18. Martin DC, Berger ML, Anstatt DT, et al. A randomized controlled open trial of population-based disease and case management in a Medicare Plus Choice health maintenance organization. *Preventing chronic disease*. Vol 1; 2004:A05.
19. Newcomer R, Maravilla V, Faculjak P, Graves MT. Outcomes of preventive case management among high-risk elderly in three medical groups: a randomized clinical trial. *Evaluation & the Health Professions*. Vol 27; 2004:323-348.
20. Boulton C, Reider L, Leff B, et al. The effect of guided care teams on the use of health services: results from a cluster-randomized controlled trial. *Arch Intern Med*. Mar 14 2011;171(5):460-466.
21. Lim WK, Lambert SF, Gray LC. Effectiveness of case management and post-acute services in older people after hospital discharge. *Medical Journal of Australia*. Vol 178; 2003:262-266.
22. Kruse RL, Zweig SC, Nikodim B, LeMaster JW, Coberly JS, Colwill JM. Nurse care coordination of older patients in an academic family medicine clinic: 5-year outcomes. *Journal of Clinical Outcomes Management*. Vol 17; 2010:209-215.
23. Dorr DA, Wilcox AB, Brunner CP, Burdon RE, Donnelly SM. The effect of technology-supported, multidisease care management on the mortality and hospitalization of seniors. *J Am Geriatr Soc*. Dec 2008;56(12):2195-2202.
24. Bird SR, Kurowski W, Dickman GK, Kronborg I. Integrated care facilitation for older patients with complex health care needs reduces hospital demand. *Australian Health Review*. Vol 31; 2007:451-461; discussion 449-450.
25. Keating P, Sealy A, Dempsey L, Slater B. Reducing unplanned hospital admissions and hospital bed days in the over 65 age group: results from a pilot study. *Journal of Integrated Care*. Vol 16; 2008:3-8.
26. Lu K-Y, Lin P-L, Tzeng L-C, Huang K-Y, Chang L-C. Effectiveness of case management for community elderly with hypertension, diabetes mellitus, and hypercholesterolemia in Taiwan: a record review. *International Journal of Nursing Studies*. Vol 43; 2006:1001-1010.
27. Luzinski CH, Stockbridge E, Craighead J, Bayliss D, Schmidt M, Seideman J. The community case management program: for 12 years, caring at its best. *Geriatric Nursing*. Vol 29; 2008:207-215.
28. Onder G, Liperoti R, Soldato M, et al. Case management and risk of nursing home admission for older adults in home care: results of the AgeD in HOME Care Study. *Journal of the American Geriatrics Society*. Vol 55; 2007:439-444.
29. Counsell SR, Callahan CM, Clark DO, et al. Geriatric care management for low-income seniors: a randomized controlled trial. *JAMA*. Dec 12 2007;298(22):2623-2633.
30. Wolff JL, Giovannetti ER, Boyd CM, et al. Effects of Guided Care on Family Caregivers. *The Gerontologist*. August 1, 2010 2010;50(4):459-470.
31. Boyd CM, Reider L, Frey K, et al. The effects of guided care on the perceived quality of health care for multi-morbid older persons: 18-month outcomes from a cluster-randomized controlled trial. *J Gen Intern Med*. Mar 2010;25(3):235-242.
32. Wolff JL, Giovannetti ER, Boyd CM, et al. Effects of guided care on family caregivers. *Gerontologist*. Aug 2010;50(4):459-470.
33. Bernabei R, Landi F, Gambassi G, et al. Randomised trial of impact of model of integrated care and case management for older people living in the community. *BMJ (Clinical research ed.)*. Vol 316; 1998:1348-1351.

34. Rubenstein LZ, Alessi CA, Josephson KR, Trinidad Hoyl M, Harker JO, Pietruszka FM. A randomized trial of a screening, case finding, and referral system for older veterans in primary care. *Journal of the American Geriatrics Society*. Vol 55; 2007:166-174.
35. Leung A-T, Liu CP, Chow N-S, Chi I. Cost-benefit analysis of a case management project for the community-dwelling frail elderly in Hong Kong. *Journal of Applied Gerontology*. Vol 23; 2004:70-85.
36. Marshall BS, Long MJ, Voss J, Demma K, Skerl KP. Case management of the elderly in a health maintenance organization: the implications for program administration under managed care. *Journal of Healthcare Management*. Vol 44; 1999:477-491; discussion 492-473.
37. Gagnon AJ, Schein C, McVey L, Bergman H. Randomized controlled trial of nurse case management of frail older people. *Journal of the American Geriatrics Society*. Vol 47; 1999:1118-1124.
38. Leung AC, Yau DC, Liu CP, et al. Reducing utilisation of hospital services by case management: a randomised controlled trial. *Australian Health Review*. Vol 28; 2004:79-86.
39. Chi Y-C, Chuang K-Y, Wu S-C, Huang K-C, Wu C-L. The assessment of a hospital-based care management model for long-term care services. *Journal of Nursing Research*. Vol 12; 2004:317-326.
40. Morales-Asencio JM, Gonzalo-Jimenez E, Martin-Santos FJ, et al. Effectiveness of a nurse-led case management home care model in Primary Health Care. A quasi-experimental, controlled, multi-centre study. *BMC Health Services Research*. Vol 8; 2008:193.
41. Hebert R, Durand PJ, Dubuc N, Tourigny A, Group P. Frail elderly patients. New model for integrated service delivery. *Canadian Family Physician*. Vol 49; 2003:992-997.
42. Long MJ, Marshall BS. Case management and the cost of care in the last month of life: evidence from one managed care setting. *Health Care Management Review*. Vol 24; 1999:45-53.
43. Plassman BL, Langa KM, Fisher GG, et al. Prevalence of Dementia in the United States: The Aging, Demographics, and Memory Study. *Neuroepidemiology*. 2007;29(1-2):125-132.
44. Callahan CM, Boustani MA, Unverzagt FW, et al. Effectiveness of Collaborative Care for Older Adults With Alzheimer Disease in Primary Care. *JAMA: The Journal of the American Medical Association*. May 10, 2006 2006;295(18):2148-2157.
45. Eloniemi-Sulkava U, Notkola I-L, Hentinen M, Kivelä S-L, Sivenius J, Sulkava R. Effects of Supporting Community-Living Demented Patients and Their Caregivers: A Randomized Trial. *Journal of the American Geriatrics Society*. 2001;49(10):1282-1287.
46. Eloniemi-Sulkava U, Saarenheimo M, Laakkonen M, et al. Family care as collaboration: effectiveness of a multicomponent support program for elderly couples with dementia. Randomized controlled intervention study. *Journal of the American Geriatrics Society*. Vol 57; 2009:2200-2208.
47. Jansen AP, van Hout HP, al. E. Effectiveness of case management among older adults with early symptoms of dementia and their primary informal caregivers: A randomized clinical trial. *International Journal of Clinical Nursing*. 2011.

48. Mittelman MS, Haley WE, Clay OJ, Roth DL. Improving caregiver well-being delays nursing home placement of patients with Alzheimer disease. *Neurology*. November 14, 2006 2006;67(9):1592-1599.
49. Vickrey BG, Mittman BS, Connor KI, et al. The Effect of a Disease Management Intervention on Quality and Outcomes of Dementia Care. *Annals of Internal Medicine*. November 21, 2006 2006;145(10):713-726.
50. Mittelman MS, Brodaty H, Wallen AS, Burns A. A Three-country randomized controlled trial of a psychosocial intervention for caregivers combined with pharmacological treatment for patients with Alzheimer disease: Effects on caregiver depression. *Am J Geriatr Psychiatry*. 2008;16(11):893-904.
51. Chien WT, Lee YM. A Disease Management Program for Families of Persons in Hong Kong with Dementia. *Psychiatric Services*. 2008;59(4).
52. Chu P, Edwards J, Levin R, Thomson J. The use of clinical case management for early stage Alzheimer's patients and their families. *American-Journal-of-Alzheimer's-Disease*. Vol 15; 2000:284-290.
53. Zimmer JG, Eggert GM, Chiverton P. Individual versus team case management in optimizing community care for chronically ill patients with dementia. *Journal of Aging & Health*. Vol 2; 1990:357-372.
54. Clark P, Bass DM, Looman WJ, McCarthy CA, Eckert S. Outcomes for patients with dementia from the Cleveland Alzheimer's Managed Care Demonstration *Aging & Mental Health*. 2004;8(1).
55. Newcomer R, Miller R, Clay T, Fox P. Effects of the Medicare Alzheimer's disease demonstration on Medicare expenditures. *Health Care Financing Review*. Vol 20; 1999:45-65.
56. Challis D, von Abendorff R, Brown P, Chesterman J, Hughes J. Care management, dementia care and specialist mental health services: an evaluation. *International Journal of Geriatric Psychiatry*. Vol 17; 2002:315-325.
57. Miller R, Newcomer R, Fox P. Effects of the Medicare Alzheimer's Disease Demonstration on nursing home entry. *Health Services Research*. Vol 34; 1999:691-714.
58. Mittelman M, Roth D, Haley W, Zarit S. Effects of a caregiver intervention on negative caregiver appraisals of behavior problems inpatients with Alzheimer's Disease: Results of a randomized trial. *J Gerontol B Psychol Sci Soc Sci*. 2004;59(1):27-34.
59. Mittelman M, Roth D, Coon D, Haley W. Sustained benefit of supportive intervention for depressive symptoms in Alzheimer's caregivers. *Am J Psychiatry*. 2004;161:850-856.
60. Newcomer R, Spitalny M, Fox P, Yordi C. Effects of the Medicare Alzheimer's Disease Demonstration on the use of community-based services. *Health services research*. Vol 34; 1999:645-667.
61. Duru OK, Ettner SL, Vassar SD, Chodosh J, Vickrey BG. Cost evaluation of a coordinated care management intervention for dementia. *Am J Manag Care*. 2009;15(8):521-528.
62. Commission MPA. *A Data Book: Healthcare Spending and the Medicare Program*. Washington, D.C.: Medicare Payment Advisory Commission; 2009.
63. Rosamond W, Flegal K, Furie K, et al. Heart Disease and Stroke Statistics--2008 Update: A Report From the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. January 29, 2008 2008;117(4):e25-146.

64. DeBusk RF, Miller NH, Parker KM, et al. Care management for low-risk patients with heart failure: a randomized, controlled trial.[Summary for patients in Ann Intern Med. 2004 Oct 19;141(8):I58; PMID: 15492334]. *Annals of Internal Medicine*. Vol 141; 2004:606-613.
65. Jaarsma T, van der Wal MH, Lesman-Leegte I, et al. Effect of moderate or intensive disease management program on outcome in patients with heart failure: Coordinating Study Evaluating Outcomes of Advising and Counseling in Heart Failure (COACH). *Arch Intern Med*. Feb 11 2008;168(3):316-324.
66. Kasper EK, Gerstenblith G, Hefter G, et al. A randomized trial of the efficacy of multidisciplinary care in heart failure outpatients at high risk of hospital readmission. *J Am Coll Cardiol*. Feb 6 2002;39(3):471-480.
67. Peters-Klimm F, Campbell S, Hermann K, et al. Case management for patients with chronic systolic heart failure in primary care: the HICMan exploratory randomised controlled trial. *Trials [Electronic Resource]*. Vol 11; 2010:56.
68. Sisk JE, Hebert PL, Horowitz CR, McLaughlin MA, Wang JJ, Chassin MR. Improving patient care. Effects of nurse management on the quality of heart failure care in minority communities: a randomized trial. *Annals of Internal Medicine*. Vol 145; 2006:273.
69. Laramee AS, Levinsky SK, Sargent J, Ross R, Callas P. Case management in a heterogeneous congestive heart failure population: a randomized controlled trial. *Archives of internal medicine*. Vol 163; 2003:809-817.
70. Rich MW, Beckham V, Wittenberg C, Leven CL, Freedland KE, Carney RM. A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. *N Engl J Med*. Nov 2 1995;333(18):1190-1195.
71. Riegel B, Carlson B, Kopp Z, LePetri B, Glaser D, Unger A. Effect of a standardized nurse case-management telephone intervention on resource use in patients with chronic heart failure. *Archives of Internal Medicine*. Vol 162; 2002:705-712.
72. Riegel B, Carlson B, Glaser D, Romero T. Randomized controlled trial of telephone case management in Hispanics of Mexican origin with heart failure. *Journal of Cardiac Failure*. Vol 12; 2006:211-219.
73. Rich MW, Vinson JM, Sperry JC, et al. Prevention of readmission in elderly patients with congestive heart failure: results of a prospective, randomized pilot study. *J Gen Intern Med*. Nov 1993;8(11):585-590.
74. Windham BG, Bennett RG, Gottlieb S. Care management interventions for older patients with congestive heart failure. *Am J Manag Care*. Jun 2003;9(6):447-459; quiz 460-441.
75. Gohler A, Januzzi JL, Worrell SS, et al. A systematic meta-analysis of the efficacy and heterogeneity of disease management programs in congestive heart failure. *J Card Fail*. Sep 2006;12(7):554-567.
76. Whellan DJ, Hasselblad V, Peterson E, O'Connor CM, Schulman KA. Metaanalysis and review of heart failure disease management randomized controlled clinical trials. *Am Heart J*. Apr 2005;149(4):722-729.
77. Roccaforte R, Demers C, Baldassarre F, Teo KK, Yusuf S. Effectiveness of comprehensive disease management programmes in improving clinical outcomes in heart failure patients. A meta-analysis. *Eur J Heart Fail*. Dec 2005;7(7):1133-1144.
78. Yu DS, Thompson DR, Lee DT. Disease management programmes for older people with heart failure: crucial characteristics which improve post-discharge outcomes. *Eur Heart J*. Mar 2006;27(5):596-612.

79. Wolf AM, Siadaty M, Yaeger B, et al. Effects of lifestyle intervention on health care costs: Improving Control with Activity and Nutrition (ICAN). *Journal of the American Dietetic Association*. Vol 107; 2007:1365-1373.
80. Babamoto KS, Sey KA, Camilleri AJ, Karlan VJ, Catalasan J, Morisky DE. Improving diabetes care and health measures among hispanics using community health workers: results from a randomized controlled trial. *Health Education & Behavior*. Vol 36; 2009:113-126.
81. Gary TL, Batts-Turner M, Bone LR, et al. A randomized controlled trial of the effects of nurse case manager and community health worker team interventions in urban African-Americans with type 2 diabetes. *Controlled Clinical Trials*. Vol 25; 2004:53-66.
82. Gary TL, Batts-Turner M, Yeh HC, et al. The effects of a nurse case manager and a community health worker team on diabetic control, emergency department visits, and hospitalizations among urban African Americans with type 2 diabetes mellitus: a randomized controlled trial. *Archives of internal medicine*. Vol 169; 2009:1788-1794.
83. Gary TL, Bone LR, Hill MN, et al. Randomized controlled trial of the effects of nurse case manager and community health worker interventions on risk factors for diabetes-related complications in urban African Americans. *Preventive medicine*. Vol 37; 2003:23-32.
84. Gary TL, Hill-Briggs F, Batts-Turner M, Brancati FL. Translational research principles of an effectiveness trial for diabetes care in an urban African American population. *Diabetes Educator*. Vol 31; 2005:880-889.
85. Krein SL, Klammer ML, Vijan S, et al. Case management for patients with poorly controlled diabetes: a randomized trial. *American Journal of Medicine*. Vol 116; 2004:732-739.
86. Pettitt DJ, Okada Wollitzer A, Jovanovic L, He G, Ipp E. Decreasing the risk of diabetic retinopathy in a study of case management: the California Medi-Cal Type 2 Diabetes Study. *Diabetes Care*. Vol 28; 2005:2819-2822.
87. Shea S, Starren J, Weinstock RS, et al. Columbia University's Informatics for Diabetes Education and Telemedicine (IDEATel) Project: rationale and design. *Journal of the American Medical Informatics Association : JAMIA*. Vol 9; 2002:49-62.
88. Shea S, Weinstock RS, Starren J, et al. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus. *J Am Med Inform Assoc*. Jan-Feb 2006;13(1):40-51.
89. Shea S, Weinstock RS, Teresi JA, et al. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus: 5 year results of the IDEATel study. *Journal of the American Medical Informatics Association*. Vol 16; 2009:446-456.
90. Wolf AM, Conaway MR, Crowther JQ, et al. Translating lifestyle intervention to practice in obese patients with type 2 diabetes: Improving Control with Activity and Nutrition (ICAN) study. *Diabetes Care*. Vol 27; 2004:1570-1576.
91. Dissemination. Closing the gap: effect of diabetes case management on glycemic control among low-income ethnic minority populations: the California Medi-Cal type 2 diabetes study. *Diabetes care*. Vol 27; 2004:95-103.
92. Curtis J, Lipke S, Effland S, et al. Effectiveness and safety of medication adjustments by nurse case managers to control hyperglycemia. *Diabetes Educator*. Vol 35; 2009:851-856.

93. Wilson C, Curtis J, Lipke S, Bochenski C, Gilliland S. Nurse case manager effectiveness and case load in a large clinical practice: implications for workforce development. *Diabetic Medicine*. Vol 22; 2005:1116-1120.
94. Dorr DA, Wilcox A, Donnelly SM, Burns L, Clayton PD. Impact of generalist care managers on patients with diabetes. *Health Services Research*. Vol 40; 2005:1400-1421.
95. Dorr DA, Wilcox A, Donnelly SM, Burns L, Clayton PD. Specialist and generalist services. Impact of generalist care managers on patients with diabetes. *Health Services Research*. Vol 40; 2005:1400-1421.
96. Jaana M, Paré G. Home telemonitoring of patients with diabetes: a systematic assessment of observed effects. *J Eval Clin Pract*. 2007;13(2):242-253.
97. Ingersoll S, Valente SM, Roper J. Using the best evidence to change practice. Nurse care coordination for diabetes: a literature review and synthesis. In: Larrabee JH, ed. *Journal of Nursing Care Quality*. Vol 20; 2005:208-214.
98. Norris SL, Messina PJ, Caspersen CJ, Engelgau MM, Jack L, Jr., Riccio KM. Strategies for reducing morbidity and mortality from diabetes through health-care system interventions and diabetes self-management education in community settings: a report on recommendations of the Task Force on Community Preventive Services. *MMWR: Morbidity & Mortality Weekly Report*. Vol 50; 2001:1-15.
99. Norris S, Nichols P, Caspersen C, et al. The effectiveness of disease and case management for people with diabetes. A systematic review. *Am J Prev Med*. 2002;22:15-38.
100. Sutherland D, Hayter M. Structured review: evaluating the effectiveness of nurse case managers in improving health outcomes in three major chronic diseases. *Journal of Clinical Nursing*. Vol 18; 2009:2978-2992.
101. Meier DE, Thar W, Jordan A, Goldhirsch SL, Siu A, Morrison RS. Integrating case management and palliative care. *Journal of palliative medicine*. Vol 7; 2004:119-134.
102. Engelhardt JB, McClive-Reed KP, Toseland RW, Smith TL, Larson DG, Tobin DR. Effects of a program for coordinated care of advanced illness on patients, surrogates, and healthcare costs: a randomized trial. *Am J Manag Care*. Feb 2006;12(2):93-100.
103. Goodwin JS, Satish S, Anderson ET, Nattinger AB, Freeman JL. Effect of nurse case management on the treatment of older women with breast cancer. *Journal of the American Geriatrics Society*. Vol 51; 2003:1252-1259.
104. Moore S, Corner J, Haviland J, et al. Nurse led follow up and conventional medical follow up in management of patients with lung cancer: randomised trial. *BMJ*. Nov 16 2002;325(7373):1145.
105. McCorkle R, Benoliel JQ, Donaldson G, Georgiadou F, Moinpour C, Goodell B. A randomized clinical trial of home nursing care for lung cancer patients. *Cancer*. Sep 15 1989;64(6):1375-1382.
106. Ritz LJ, Nissen MJ, Swenson KK, et al. Effects of advanced nursing care on quality of life and cost outcomes of women diagnosed with breast cancer. *Oncol Nurs Forum*. Jul 2000;27(6):923-932.
107. Wulff CN, Thygesen M, Sondergaard J, Vedsted P. Case management used to optimize cancer care pathways: a systematic review. *BMC Health Serv Res*. 2008;8:227.
108. McCorkle R, Strumpf NE, Nuamah IF, et al. A specialized home care intervention improves survival among older post-surgical cancer patients. *J Am Geriatr Soc*. Dec 2000;48(12):1707-1713.

109. Sorensen JL, Dilley J, London J, Okin RL, Delucchi KL, Phibbs CS. Case management for substance abusers with HIV/AIDS: a randomized clinical trial. *The American journal of drug and alcohol abuse*. Vol 29; 2003:133-150.
110. Wohl AR, Garland WH, Valencia R, et al. A randomized trial of directly administered antiretroviral therapy and adherence case management intervention. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. Vol 42; 2006:1619-1627.
111. Husbands W, Browne G, Caswell J, et al. Case management community care for people living with HIV/AIDS (PLHAs). *AIDS Care*. Vol 19; 2007:1065-1072.
112. McCoy HV, Dodds S, Rivers JE, McCoy CB. Case management services for HIV-seropositive IDUs. *NIDA Research Monograph*. Vol 127; 1992:181-207.
113. Nickel JT, Salsberry PJ, Caswell RJ, Keller MD, Long T, O'Connell M. Quality of life in nurse case management of persons with AIDS receiving home care. *Research in Nursing & Health*. Vol 19; 1996:91-99.
114. Kushel MB, Colfax G, Ragland K, Heineman A, Palacio H, Bangsberg DR. Case management is associated with improved antiretroviral adherence and CD4+ cell counts in homeless and marginally housed individuals with HIV infection. *Clinical Infectious Diseases*. Vol 43; 2006:234-242.
115. Andersen M, Hockman E, Smereck G, et al. Retaining women in HIV medical care. *Journal of the Association of Nurses in AIDS Care*. Vol 18; 2007:33-41.
116. Lehrman SE, Gentry D, Yurchak BB, Freedman J. Outcomes of HIV/AIDS case management in New York. *AIDS Care*. Vol 13; 2001:481-492.
117. Nyamathi AM, Christiani A, Nahid P, Gregerson P, Leake B. A randomized controlled trial of two treatment programs for homeless adults with latent tuberculosis infection. *International Journal of Tuberculosis & Lung Disease*. Vol 10; 2006:775-782.
118. Mangura B, Napolitano E, Passannante M, et al. Directly observed therapy (DOT) is not the entire answer: an operational cohort analysis. *International Journal of Tuberculosis & Lung Disease*. Vol 6; 2002:654-661.
119. Lin R-L, Lin F-J, Wu C-L, Peng M-J, Chen P-J, Kuo H-T. Effect of a hospital-based case management approach on treatment outcome of patients with tuberculosis. *Journal of the Formosan Medical Association*. Vol 105; 2006:636-644.
120. Hsieh CJ, Lin LC, Kuo BI, Chiang CH, Su WJ, Shih JF. Exploring the efficacy of a case management model using DOTS in the adherence of patients with pulmonary tuberculosis. *J Clin Nurs*. Apr 2008;17(7):869-875.
121. Sansom SL, Anthony MN, Garland WH, et al. The costs of HIV antiretroviral therapy adherence programs and impact on health care utilization. *AIDS Patient Care & STDs*. Vol 22; 2008:131-138.
122. Tatum WO, Al-Saadi S, Orth TL. Outpatient case management in low-income epilepsy patients. *Epilepsy Research*. Vol 82; 2008:156-161.
123. Wetta-Hall R. Impact of a collaborative community case management program on a low-income uninsured population in Sedgwick County, KS. *Applied Nursing Research*. Vol 20; 2007:188-194.
124. Ma J, Berra K, Haskell WL, et al. Case management to reduce risk of cardiovascular disease in a county health care system. *Archives of internal medicine*. Vol 169; 2009:1988-1995.

125. Berra K, Ma J, Klieman L, et al. Implementing cardiac risk-factor case management: lessons learned in a county health system. *Critical pathways in cardiology*. Vol 6; 2007:173-179.
126. Ma J, Berra K, Haskell WL, et al. Case management to reduce risk of cardiovascular disease in a county health care system. *Arch Intern Med*. 2009;169(21):1988-1995.
127. Sadowski LS, Kee RA, VanderWeele TJ, Buchanan D. Effect of a housing and case management program on emergency department visits and hospitalizations among chronically ill homeless adults: a randomized trial. *JAMA*. Vol 301; 2009:1771-1778.
128. Chow SKY, Wong FK. Health-related quality of life in patients undergoing peritoneal dialysis: effects of a nurse-led case management programme. *Journal of Advanced Nursing*. Vol 66; 2010:1780-1792.
129. Claiborne N. Efficiency of a care coordination model: a randomized study with stroke patients. *Research on Social Work Practice*. Vol 16; 2006:57-66.
130. Allen KR, Hazelett S, Jarjoura D, et al. Effectiveness of a postdischarge care management model for stroke and transient ischemic attack: a randomized trial. *Journal of Stroke & Cerebrovascular Diseases*. Vol 11; 2002:88-98.

Abbreviations

ADL	Activities of daily living
AHRQ	Agency for Healthcare Research and Quality
APN	Advanced practice nurses
BMI	Body mass index
BP	Blood pressure
CER	Comparative Effectiveness Review
CHF	Congestive heart failure
CHW	Community health worker
CM	Case management
COPD	Chronic obstructive pulmonary disease
DBP	Diastolic blood pressure
DM	Diabetes mellitus
ED/ER	Emergency department/emergency room
EPC	Evidence-based Practice Center
FTF	Face-to-face
HDL	High-density lipoprotein cholesterol
HgA1c	Hemoglobin A1c
HMO	Health Maintenance Organization
IADL	Instrumental activities of daily living
LDL	Low-density lipoprotein cholesterol
LTBI	latent tuberculosis infection
MCCD trial	Medicare Coordinated Care Demonstration trial
MCO	Managed care organization
NP	Nurse practitioner
NPI	neuropsychiatric inventory
NR	Not reported
NYHA	New York Heart Association
PS	Psychosocial
QOL	Quality of life
RD	Registered dietitian
RN	Registered nurse
SBP	Systolic blood pressure
SF-36	Short form 36
SNF	Skilled nursing facility
SW	Social worker
TB	Tuberculosis
TC	Total cholesterol
TEP	Technical Expert Panel
TOO	Task Order Officer
U.K.	United Kingdom
U.S.	United States
VAMC	Veterans Affairs Medical Center